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HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUITIONAL REVIEW BOARD

POLICIES AND PROCEDURES MANUAL

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HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

INSTITUTIONAL AUTHORITY AND PURPOSE

I. INSTITUTIONAL AUTHORITY.

This Charter and Standard Operating Procedures establishes and empowers the Harrisburg University of Science and Technology (HU) human subjects protection committee. This committee is hereinafter referred to as "the IRB." The HU IRB is registered with the federal Office for Human Research Protections (OHRP) as an Institutional Review Board. Registration with the FDA will be pursued if HU participates in any research using FDA-regulated items.

II. PURPOSE.

The primary purpose of the IRB is to protect the welfare of human subjects used in research. In addition, the IRB develops and publishes guidelines on the use of human subjects in research.

III. BASIC PRINCIPLES.

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"), The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at HU to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate and presented in lay language appropriate to the subject population.

7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review committee *prior* to their initiation or *prior* to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

IV. THE AUTHORITY OF THE IRB.

A. HU agrees to consider *all* research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which HU has an "IRB Authorization Agreement"), or

2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which HU has an "IRB Authorization Agreement"), or

3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to discuss the protocol with the IRB Chair and, if deemed necessary, complete a written research protocol for approval and submit it along with any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance or approval of the IRB regarding these activities.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Provost. However, the Provost may not approve the research if it has not been approved by the IRB.

   The minutes of the IRB convened meetings reflect all actions taken by the IRB at that meeting. These minutes are approved by the IRB at the following meeting. Once approved, these minutes may not be altered, including by any higher authorities at HU.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS.

A. The IRB functions administratively through the Provost. This structure provides for administrative coordination for the IRB with the various units in the university.

B. The IRB advises and makes recommendations to the President, to policy and administrative bodies, and to any member of the university community on all matters related to the use of human subjects in research.

C. Policies and procedures developed for human subject research are approved by the Provost and the current IRB Chair. All policies will be presented to the current IRB members for their input and concurrence. This will be reflected in the minutes of the meeting.

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

MEMBERSHIP

I MEMBERSHIP CRITERIA

A. The IRB is composed of at least 5 voting members. All appointments are made by the Provost. Appointment is for a three-year term, however tenure may be extended by mutual agreement between the member and the IRB Chair.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of University regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed, in accordance with following procedure:

1. Each research protocol submitted to the IRB is reviewed prior to being scheduled for initial review to determine whether special expertise is needed.

2. The determination of whether special expertise is needed is made by the IRB Chair on the basis of the following criteria: the availability of behavioral expertise for the review of behavioral studies, and the availability of individuals (IRB members or consultants) with experience with particular vulnerable populations (e.g. cognitively impaired, children). When IRB members have appropriate qualifications to allow them to represent vulnerable populations this is indicated on the membership roster. No action can be taken on protocols involving vulnerable populations without the participation of an IRB member or consultant representing the population participating in the study.

3. Experts are selected by the IRB Chair from the IRB's roster of members or from recommendations of outside consultants provided by IRB members.

4. If an IRB member is selected, his or her feedback is included in their normal review of the protocol. If a consultant is selected, his or her feedback is in the form of a written report that is shared with IRB members as soon as practical before the initial review of the protocol.

5. A licensed physician committee member must be present before voting can occur on research involving a FDA-regulated article.

C. The IRB includes both men and women, at least two licensed physicians, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the University. Note: An individual is considered to be 'affiliated' if he or she is a current or former employee or family member of any current or former employee, retiree,

trainee, consultant, or board member of HU; or if that person's relationship with the institution is anything other than that of an IRB member.

Officials of HU whose responsibilities include developing or allocating research resources or overseeing the research program may consult with the IRB but may not serve as voting members. One individual may fulfill more than one of the requirements listed above, i.e., a member who is a non-scientist and also unaffiliated fills both requirements for membership.

D. No person is excluded from serving on the IRB based on sex, race, color or national origin.

E. The IRB Chair, in consultation with the Provost, periodically reviews the composition of the IRB to ensure that the foregoing guidelines are met. In the event that any necessary changes to the IRB membership are identified during such review, the IRB Chair shall notify the Provost, along with recommendation(s) for modification(s) to the membership to accomplish such changes. The Provost will approve all recommendations and notify the appointee.

II ALTERNATE MEMBERS

A. Alternate members may be appointed to the IRB and are listed on the membership roster of the IRB along with the name(s) or class(es) of IRB members for whom the alternate may serve. An alternate member thus appointed must possess qualifications that are comparable to those of the IRB member(s) for whom the alternate will serve. The alternate member will receive and review the same material that the primary member has received.

B. Alternate members serve only when the member for whom the alternate is appointed cannot attend a convened meeting of the IRB. When the alternate member substitutes for the regular member at a convened meeting, the alternate is counted in the quorum and has voting privileges.

III MEMBERSHIP DOCUMENTATION

A. A current roster of all IRB members, in addition to the *curriculum vitae* of each member, is kept in the files in the IRB office, and contains the following information:

a. Name
b. Degrees earned
c. Gender
d. Representational capacity (scientist; non-scientist)
e. Relationship to the institution (affiliated; non-affiliated)
f. Identification of specific role, if any, e.g., chair, vice-chair, specified alternate,
g. Advocate role, or other specific role

If a member resigns prior to the expiration of the term of membership, the IRB Chair shall, with all due speed, appoint a new member to complete the term of membership. Consideration shall be given to current alternate members and to any special expertise required among IRB membership.

IV THE IRB CHAIR

The IRB Chair is appointed by the President of the University based on recommendation received from the Provost. Any individual appointed as Chair of the IRB shall have served as an IRB member prior to the appointment as Chair and shall demonstrate knowledge of human subjects' protections. The IRB Chair is a voting member of the IRB and presides over all convened IRB meetings. The Chair has authority to sign all IRB action items.

The IRB chair will be evaluated every year by the Provost. The Provost will seek input from the IRB members serving under the chair during the annual evaluation. The IRB chair is initially appointed to a three-year term by the Provost and the President of the University. The IRB chair may serve multiple terms.

V THE IRB VICE-CHAIR

The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair with the concurrence of the IRB, and has authority to sign all IRB action items in the absence of the Chair.

VI TRAINING

All members and all alternates must complete the demonstration of knowledge of human research protection. Currently this training is provided through the Collaborative Institutional Training Institute (CITI) on-line course. The IRB Chair will maintain a log of training completion dates. Retraining will be done every three years. A newly appointed member must complete an orientation in human subjects protection and IRB procedures prior to casting a vote at a convened IRB meeting. The IRB chair and IRB coordinator are responsible for delivering new member orientation.

Continuing education of IRB members is accomplished through "Information Items" attached to meeting agendas on an "as needed" basis, through educational topics (e.g. procedure reviews) presented at convened meetings, and through maintenance of CITI training.

IRB members do not receive compensation for their service.

VII INITIAL AND ANNUAL REVIEW OF QUALIFICATIONS OF IRB MEMBERS

The IRB Chair performs an initial and annual review of the qualifications of each member of the IRB. The review includes consideration of each of the following factors: (a) currency of that member's training in human subjects research; (b) currency of conflict-of-interest disclosures; (c) current expertise (when applicable); (d) employment status of any unaffiliated member or members of his/her family; and (e) other factors as required to ensure that the IRB retains appropriate composition. The Chair shall communicate any required actions identified by such review to the affected member for action.

If a member finds that he/she is unable to attend meetings for an extended period, the IRB Chair must be informed so that a replacement may be considered. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for unwillingness or incapability to serve the committee adequately.

VIII CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

A. An IRB member (or consultant) is said to have a conflicting interest whenever that IRB member (or consultant), or spouse, or dependent child of the member:
    1. Is an investigator or sub-investigator on the protocol; or is involved in the design, conduct or reporting of the research.
    2. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest. This would include situations where the member or consultant has an ownership interest that would be affected by the outcome of the research:
        i. Has ownership interest, stock options, or other financial interest related to the research of $10,000 or greater value when referenced to publicly traded prices or other measure of fair market value when aggregated for the immediate family and whose value would be affected by the outcome of the research
        ii. Has ownership interest (equity or stock options) related to the research whose value when aggregated for immediate family represented 5% or more interest in any one single entity
        iii. Has ownership interest, stock options, or other financial interest related to the research whose value could not be determined through reference to publicly available prices
        iv. Receives compensation related to the research whose amount would be affected by the outcome of the research
    3. Has a financial interest in non-sponsored research
    4. Has proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
    5. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
    6. Has Board or executive relationship to the research, regardless of compensation

7. Has a personal or financial relationship with a firm that is in competition with the company sponsoring the research to be reviewed
8. Has identified him or herself for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Upon initiation of the convened IRB, the IRB Chair will query IRB members (consultants) to determine if they have a conflict of interest with respect to any items they reviewed and have them specify what construes their conflict of interest. It will be at the discretion of the IRB Chair that the member (s) who have a real or perceived conflict of interest remain in the meeting room during discussion of the identified item, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room prior to deliberations and actions/votes regarding the item.

D. In the event that a conflict of interest with an IRB member is discovered after research has been approved, the research protocol will be suspended until an inquiry has been completed and the protocol is reapproved by the IRB.

E. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest. On items in which an IRB member has a conflict of interest., the member will not be counted towards a committee quorum

F. IRB members will, at the beginning of their service on the IRB, and annually thereafter, report their potential conflicts of interest by filling out the IRB Conflict of Interest form (see appendix).

IX LIABILITY COVERAGE FOR IRB MEMBERS

A. Liability coverage for IRB members is provided through HU's liability insurance coverage, whether or not the IRB member is an employee of HU.

X APPLICABLE REGULATIONS:

45 CFR 46.107

21 CFR 56.107

Appendix

IRB MEMBER CONFLICT OF INTEREST FORM

1. As an IRB member/alternate member, do you have a vested interest in any actual or *potential* commercial enterprise/business, other than patents, which may be germane to conducting research protocol reviews?

   ☐ Yes ☐ No

   If yes, fully explain and identify the safeguards taken to prevent bias in review: ☐

2. Are there financial issues that may be of concern to conducting an impartial review? If no, please certify this by checking the following boxes to indicate that you, as an IRB reviewer/ committee member:

   ☐ Do not have ownership interest, stock options or other financial interest related to any proposed research whose value, when aggregated for immediate family, represents ≥5% interest in any one single entity

   ☐ Will not receive compensation related to the research whose amount is affected by the outcome of the research

   ☐ Have no equity interests in the sponsor of studies greater than $10,000 (when aggregated for the immediate family), **or** do not have ownership interest, stock options, or other financial interest related to the proposed research of any value whose value could not be determined through reference to publicly available prices

   ☐ Do not have Board or executive relationship related to proposed research, regardless of compensation

   ☐ Will receive no payments by research sponsors directly to the investigator(s), their spouses or dependent children

   ☐ Have no financial interests (other than patents) in any non-sponsored research

   If all boxes above cannot be checked, please describe below (or in a separate attachment) how such financial arrangements will not adversely affect the interests of the research subjects, and how subjects will be given any information which may be material to potential subjects' decision-making process.
   ☐

3. Do you agree to excuse (recuse) yourself on a case-by-case basis, in any matter coming before the IRB committee in which you may have a potential or real conflict of interest?

   ☐ Yes ☐ No

   Committee member: _____ Date: _____
   (Print Name)

   Signature _____

   The above should be filled out yearly, as applicable, and submitted to the IRB Chair

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD
INSTITUTIONAL AUTHORITY AND PURPOSE

EXEMPTION DETERMINATIONS AND EXPEDITED REVIEW POLICY

All proposed research involving human subjects must be submitted to the IRB for review. The IRB Chair is responsible for screening new submissions to confirm that the proposed research meets the definition of human subject research (see below) prior to initiating IRB review.

If a faculty advisor is unsure whether or not his/her own or a student's proposed research meets the definition, he/she should consult with the IRB Chair or Administrator.

The purpose of this policy is to describe the process by which exemption determinations and expedited review are conducted at HU.

I DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

I*ntervention* means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction means communication or interpersonal contact between investigator and subject.

Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Minimal Risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

II EXEMPT DETERMINATIONS

Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. IRB staff members are responsible for screening new studies to determine whether or not the proposed research requires IRB review or qualifies for an exempt determination.

The reviewing IRB staff member has the authority to make an exempt determination, but may consult with the IRB Chair or an IRB member if he/she needs assistance in determining whether or not the proposed research meets an exemption category listed below.

FDA-regulated research does not qualify for an exemption unless it falls under the FDA's emergency use provision for the use of a test article (21 CFR 56.104(c)) or Taste and Food Quality Evaluations and Consumer Acceptance Studies Exempt Category 6(21 CFR 56.104(d)).

There are exemption restrictions for research involving children (see 45 CFR 46, Subpart D); and research involving prisoners will not qualify as exempt research (see 45 CFR 46, Subpart C). In addition, any HHS- funded research using newborn dried blood spots collected on or after March 18, 2015 will also not qualify as exempt research: (see NOTOD-12-127 Preliminary Guidance Related to Informed Consent for Research on Dried Blood Spots Obtained Through Newborn Screening).

After the review is complete, the study's PI/faculty advisor will be notified in writing if his/her study has been determined to be exempt from IRB review. The exemption letter must document the date that exemption was made and the applicable exemption category or categories.

Human subject research that is exempt from IRB review does not require continuing review. However, the PI/faculty advisor must consult with an IRB staff member prior to making any substantive changes to the initial research plan to determine whether the modified research plan remains exempt or requires IRB review. IRB records for exemption determinations will be maintained for a minimum of three years.

III IRB NOTIFICATION OF EXEMPTIONS

At each convened meeting, the IRB will review the Report of Administrative Actions that includes a list of all studies that were determined to be exempt (including exemption category) since the last IRB meeting. The IRB will make the determination whether to accept exemptions listed on the report. If the IRB votes not to accept any of the exemptions, then the studies must be brought to a subsequent convened meeting for additional review and discussion. If no additional review is requested at the convened meeting, the IRB will vote to approve the written notification and the Report will be appended to the meeting minutes as documentation of this approval.

Exempt Categories: 45 CFR 46.101(b) (1-6); 45 CFR 46.401(b); 21 CFR 56.104(d)

Exempt Category 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

 Research on regular and special education instructional strategies; or

 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

 Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

 Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation..

Exempt Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

 The human subjects are elected or appointed public officials or candidates for public office; or

 Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exempt Category 5

Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs: (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those program.

Exempt Category 6

Taste and food quality evaluation and consumer acceptance studies,

 If wholesome foods without additives are consumed; or

 If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Informed Consent and HIPAA Authorization Requirements

Written informed consent is not required for research determined to be exempt from IRB review. However, the IRB encourages investigators to provide potential subjects with information about the study (e.g., informational letter) whenever feasible prior to engaging any subject in that research as a way to support their voluntary participation.

If the proposed research involves utilization of Protected Health Information (PHI), HIPAA regulations still apply, even if the IRB staff member has determined that the research is exempt. Investigators must indicate whether the research involves PHI as part of the initial application process and apply for a waiver of authorization if written authorization will not be obtained from each subject in accordance with the Privacy Rule.

IV EXPEDITED REVIEW

Definition

The HU IRB uses an expedited review process to review studies that meet the expedited categories adopted by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), and that involve no greater than "minimal risk." Expedited review procedures can also be utilized for the review of minor revisions submitted for previously approved research during the period for which approval is authorized.

The expedited review process can be carried out by the Chair of the IRB or one or more experienced reviewers designated by the Chair from among voting members of the IRB. Federal regulations also dictate that when an IRB uses expedited review procedures, there must be a mechanism in place for advising all the members of the IRB of the research procedures approved under this review process.

Authority of an Expedited Reviewer

The expedited reviewer is responsible for ensuring that all the information requested in the Initial Review application is provided. The expedited reviewer make the final determination as to whether research activities meet the expedited review criteria as outlined in the section of this document titled, Definition of Minimal Risk and Guidance to PI and Reviewers.

The expedited reviewer also determines whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111. (See Criteria for IRB approval: Reviewer Checklist.)

The expedited reviewer has the authority to approve a study or request additional information. The expedited reviewer does not have the authority to disapprove a study.

Informed Consent

Expedited reviewers ensure that the investigator conducts the informed consent process and obtains documentation of informed consent, as specified in 45 CFR 46.116 and 117, 21 CFR 50.25, and 38 CFR 16.116 and 117, unless the IRB waives the requirements in accord with federal regulations. When children are involved as research subjects, the expedited reviewer is also charged with ensuring that there are adequate provisions for obtaining assent from these children.

Vulnerable Subject Populations

Federal regulations do not specify whether any certain populations should be globally excluded from a study for it to be eligible for expedited review. The expedited reviewer gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and decisionally challenged/impaired persons. The expedited reviewer also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation.

Definition of Minimal Risk and Reviewer Guidance

Expedited procedures can only be used to review a study if the only involvement of human subjects fits one or more of the categories specified in the federal regulations and if all the procedures present no greater than "minimal risk." The IRB reviewer confirms that all the research activities fit in one or more of the expedited categories. If the research includes activities that do not fit in the categories, the study is not eligible for expedited review even if the research involves "minimal risk."

The Department of Health and Human Services defines **minimal risk** to mean "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(2)(i)].

Investigators are asked to provide a risk assessment, but it is the IRB reviewer's responsibility to determine whether the research meets the federal definition.

The IRB reviewer must consider two questions:

♦ Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?

♦ Is the magnitude of the harm or discomfort greater than that encountered ordinarily in the daily life or during the performance of routine physical or psychological examinations or tests?

If the answer is "yes" to either of these questions, then the research does not meet the definition of minimal risk.

Federal Expedited Review Applicability and Categories

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB. (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Expedited Research Categories

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

    b. From other adults and children1 considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the

frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey,

interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:

   a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   b. Where no subjects have been enrolled and no additional risks have been identified; or

   c. Where the remaining research activities are limited to data analysis.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Minor Modifications Submitted for Previously Approved Research

Investigators must report to the IRB any proposed changes in IRB-approved research, including proposed changes in informed consent documents. No changes may be initiated without approval of the IRB, except where necessary to eliminate apparent immediate hazards to subjects.

In accordance with 45 CFR 46.110(b) (2), 38 CFR 16.110(b) and 21 CFR 56.110, IRBs may utilize expedited procedures to review a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

A minor modification is one that, in the judgment of the IRB reviewer, makes **no substantial alteration** in:

(1) The level of risk to subjects;
(2) The research design or methodology;
(3) The subject population;
(4) The qualifications of the research team;
(5) The facilities available to support the safe conduct of the research;
(6) Any other factor that would warrant review of the proposed changes by the convened IRB.
Examples of minor modifications include but are not limited to:

- Changes in study research personnel;
- Adding a blood draw to a research study;
- Decreasing the amount of a blood drawn or the frequency of blood drawn;
- Adding research site(s) to a research study (assuming they are of a similar nature to those previously approved by the IRB);
- Adding a standardized test instrument to a research study;
- Modifying the subject recruitment plan;
- Adding a standard quality of life questionnaire;
- Extending the time period of the study to include follow-up with the research participants (with no additional invasive measures such as blood withdrawals);
- Changing the principal investigator (assuming the proposed PI has similar credentials to the previously approved P.I.);
- Deletion of questions in a questionnaire;
- Adding "non-sensitive" questions (questions that would not appear to invoke psychological injury) to a questionnaire;
- Changing telephone numbers or contact persons on the consent form
- Changing the dates of time for initiating a study;
- Modifications in an already approved subject recruitment flyer;
- Changes in project title;
- Adjusting incentives (so long as these do not appear coercive).

Expedited Reviewer Responsibilities

IRB members will be assigned as expedited reviewers for submissions based on the Reviewer Schedule maintained by the IRB Office. **All expedited reviews should be conducted within 14**

days of receipt. A reviewer must notify the IRB Office ASAP if he/she will be unable to complete the review within 14 days so that the item can be reassigned reviewer. However, it is expected that reviewers will be available to conduct timely reviews during their assigned review period.

The study's PI/faculty advisor will be notified in writing if his/her study has been approved via expedited review. The expedited approval letter must document the study approval date, study expiration date, expedited review category, any informed consent or HIPAA authorization waivers, and any required findings with regard to vulnerable populations (e.g., children, pregnant women, prisoners, etc.…).

IRB Notification of Expedited Reviews

At each convened meeting, the IRB will review the Report of Administrative Actions that includes a list of all studies that were reviewed using expedited procedures (including the applicable expedited category) since the previous meeting. The IRB will make the determination whether to accept expedited reviews listed on the report. If the IRB votes not to accept any of the expedited reviews, then the studies must be brought to a subsequent convened meeting for additional review and discussion. If no additional review is requested at the convened meeting, the IRB will vote to approve the written notification and the Report will be appended to the meeting minutes as documentation of this approval.

HU IRB EXEMPT DETERMINATION CHECKLIST

If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is "True" (except where noted), the research can be determined exempt from IRB review by the assigned IRB Reviewer.

Checklist Statement	True √	Not True √
☐ **Category 1: For Educational Settings:**		
The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.)		
2* The research will involve only normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.		
3* The research will not involve individuals as participants who are known to be prisoners.		
4* The research is not subject to FDA regulations.		
☐ **Category 2: For Educational Tests, Surveys, Interviews, Public Behavior Observations**		
5* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.		
6* **Address statement 6 only if the research will involve children (defined as <18 years old) as participants. If children will NOT participate, indicate N/A and continue with statement 7.** Children are involved and the procedures will be limited to observation of public behavior where the investigator will NOT participate in the activities being observed.		
7* The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. **'True' to either statement 7 or 8 will qualify for exemption if statements 9 and 10 are true.**		
8* Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.		
		Not

Checklist Statement	True √	True √
9* The research will not involve individuals as participants who are known to be prisoners.		
10* The research is not subject to FDA regulations.		
☐ **Category 3: Public Officials - Educational Tests, Surveys, Interviews, Public Behavior Observation**		
11* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.) **'True' to either statement 11 or 12 will qualify for exemption if statements 13 and 14 are true.**		
12* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.		
13* The research will not involve individuals as participants who are known to be prisoners.		
14* The research is not subject to FDA regulations.		
☐ **Category 4: Existing Data, Documents and Specimens**		
The research will involve only the collection or study of ***existing*** data, documents, records, pathological specimens, or diagnostic specimens. ("Existing" means existing before the research is proposed to the IRB to determine whether the research is exempt. All materials to be reviewed currently exist at the time of this exemption request.)		
The sources of the existing data, documents, records or specimens are publicly available **OR** the information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them.		
The research will not involve individuals as participants who are known to be prisoners.		
The research is not subject to FDA regulations.		

Checklist Statement	True √	Not True √
☐ **Category 5: Federal Public Benefit or Service Programs**		
The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those public benefit or service programs.		
The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
The research is not subject to FDA regulations.		
The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).		
The research or demonstration project will be conducted pursuant to specific federal statutory authority.		
There is no statutory requirement that the project be reviewed by an IRB.		
The project does not involve significant physical invasions or intrusions upon the privacy of participants.		
The exemption has authorization or concurrence by the funding agency.		
☐ **Category 6: Taste and Food Quality and Consumer Acceptance Studies**		
The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **<u>OR</u>** (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.		
The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
☐ HIPAA: If the research involves protected health information (PHI), the investigator provided adequate justification to waive authorization or is obtaining written authorization. Note that if study investigator accesses PHI but doesn't record identifiers, the research still involves PHI.		

OPERATIONS OF THE INSTITUTIONAL REVIEW BOARD

I MEETING PREPARATION

A. There should be at least one IRB meeting scheduled every four (4) months.

B. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

C. Assignment of Reviewers

1. New Protocols

The IRB Chair will evaluate each protocol and will assign one primary reviewer with appropriate scientific expertise to conduct an in-depth review of the protocol and at least one secondary reviewer for each new protocol, both of whom will receive the complete study documentation for review. The primary and secondary reviewers receive the following materials for review:

- The Application To Use Human Subjects In Research form
- The Study Protocol
- Informed Consent Document(s)
- Materials for Subjects (i.e. questionnaires, surveys; if applicable)
- Subject Recruitment Advertising Copy (if applicable)
- The relevant Grant Application (if applicable)

The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that protocol.

The other members of the convened IRB receive the following items in the reviewer packet prior to each meeting:

- The Application To Use Human Subjects In Research form
- Informed Consent Document(s)
- Materials for Subjects (i.e. questionnaires, surveys; if applicable)
- Subject Recruitment Advertising Copy (if applicable)

2. Continuing Reviews

The IRB assigns two primary reviewers for each protocol undergoing continuing review. The frequency of review will be determined based upon a risk assessment and will occur no less frequently than yearly. For instance, the IRB may require more frequent reviews based on degree of risk, the inclusion of any vulnerable populations, occurrence of problems with the research, and determination of non-compliance. These factors will all be taken into consideration when determining the length of the interval for review.

Reviewers are assigned consistent with protocol content and review expertise. All IRB members receive the documentation supplied by the Investigator as described in the policy for Continuing Review. Complete copies of all materials submitted with the original application, as well as any modifications/amendments are available to all members of the IRB. Upon request these will also be brought to the meeting where the Continuing Review is discussed.

II VOTING REQUIREMENTS

A. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas. If a quorum is lost during a meeting, the convened IRB cannot take votes until it is restored.

B. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone or video conference call are permitted.

C. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

D. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If, during an IRB meeting the Chair moves the meeting to Executive Session, then any visitors will be asked to leave the room until the Executive Session has ended.

E. All actions of the IRB will be communicated to the Principal Investigator in written form. This communication will include the decision of the IRB (Approval, Approval with restrictions or Disapproval), a listing of any restrictions, and, if the research is disapproved, a summary of the reason(s) for disapproval, and information on how the Principal Investigator can appeal the decision. Restrictions may be lifted and approval granted once the revisions have been reviewed by the IRB Chair. In addition, the IRB may defer a decision, and request (in writing) that the investigator supply additional information to assist the IRB in making its decision. The IRB may also invite an investigator to attend the IRB meeting to answer questions for the IRB.

III APPEALS

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc*

committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established in the policies of the IRB and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

IV MINUTES

A. Complete minutes of all convened IRB meetings are taken by the designee of the IRB Chair.
B. Minutes are provided to all committee members prior to the subsequent meeting for their review prior to the meeting.
C. Minutes are approved by the committee at the subsequent meeting. Once approved, they may not be altered by anyone, including any higher institutional authorities.
D. The IRB coordinator will provide a copy of the minutes to the Provost within 3 weeks of the meeting date.
E. Minutes include the following elements:
    1. Member attendance at the meeting, including when an alternate member has replaced a primary member, and (if both are present) which is being counted for purposes of establishing a quorum
        a. Note – although members do not routinely participate via teleconference, this option is allowable. If members do participate by teleconference, the minutes need to document this, as well as document that these members received pertinent material prior to the meeting, and were able to actively and equally participate in discussions.
    2. Visitor attendance at the meeting
    3. Roles (e.g. community representative, representative of vulnerable populations) of each person present at meeting, including any alternate members who are replacing primary members at the meeting
    4. Any changes in attendance for each action taken by the committee (e.g. changes due to members who have left or joined during the meeting). Names of members will be recorded as changes in attendance occur. If members have absented or recused themselves due to a conflict of interest, the member name and this reason are recorded in the minutes.
    5. A summary of any controversial issues and their resolution
    6. For any protocol requiring revision prior to approval, a complete summary and justification of all items requiring modification in sufficient depth to allow the researcher to address the areas of concern to the committee
    7. For any protocol that is disapproved, the basis for disapproving research will be clearly recorded.
    8. If applicable, a justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the consent document
    9. If applicable, the rationale for significant risk/nonrisk device determinations
    10. A determination of the level of risk
    11. Specific determinations, as required by the regulations, and protocol-specific findings justifying those determinations for:
        a. Waiver or alteration of the consent process or documentation of consent

   b. Waiver or alteration of the HIPAA authorization requirements for use of protected health information
   c. Research involving prisoners, pregnant women, human fetuses and neonates, and children
12. A decision on the protocol (approval, approval with restrictions, disapproval, table pending clarification from the principal investigator) and the length of the approval period. This will include the specific number of votes for each protocol as numbers for, against, abstaining, and recusal (and reason for recusal).
13. A decision on the body responsible for reviewing the principal investigator's response to a protocol which has been approved with restrictions by the IRB
    a. Review and approval may be granted by the IRB chair or designee
    b. Review and approval will be granted only following full board review of the modified protocol
14. A record of approval of all actions taken by the IRB chair or designee on exempt or expedited research. This will also include the specific category used to determine exemption for protocols categorized as exempt.
15. A record of all protocols that were contingently-approved at a prior meeting and that have since fulfilled the requirements for approval as specified by the IRB
16. Reports of significant adverse events or unanticipated problems and a determination if these are serious, unanticipated and research-related (for adverse events) or (for unanticipated problems) if these involve noncompliance, and/or are serious and continuing in nature.

V RECORDS RETENTION

1. All materials required by regulatory authorities will be maintained for at least three years.
2. All records relating to research that is conducted shall be retained for at least three years after completion of the research.
3. At a minimum, the following regulatory-required materials will be maintained for at least three years:
4. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
5. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
6. Records of continuing review activities (see below).
7. For a protocol's initial and continuing review, documentation will include the frequency of the next continuing review.
8. For initial and continuing review of research by the expedited procedure, documentation will be maintained indicating:
   a. The specific permissible category.

   b. Description of action taken by the reviewer.

c. Any findings required under the regulations.

d. Copies of all correspondence between the IRB and the investigators.

e. A list of IRB members in the same detail as described in §46.103(b)(3).

f. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

9. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).
10. Records shall be accessible for inspection and copying by authorized representative of the Department of Health and Human Services, the Food and Drug Administration, and other federal regulatory agencies at reasonable times and in a reasonable manner.
11. All forms submitted or retained as evidence of informed consent for studies involving more than minimal risk to subjects must be preserved by the investigator indefinitely. Should a PI leave the university, signed consent forms are to be transferred to the IRB for storage.

VI SELF-ASSESSMENT

1. There is no required external audit of the IRB performed at this time.

2. At least once every three years, the IRB Chair will conduct a self-assessment. Deficiencies identified with this assessment will be brought to the attention of the IRB members and the Provost.

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

SUBMISSION OF NEW PROTOCOLS FOR REVIEW

Requirements for submission of new protocols for review by the HU IRB are included on the Application To Use Human Subjects In Research form. In addition, this web site includes helpful suggestions for preparing and submitting the petition and required accompanying documentation.

I REQUIREMENTS

A. Requirements for submission include the following:

B. Professional qualifications to perform the research, including a description of necessary support services and facilities. Curriculum Vitae of all investigators are needed if not previously submitted to the IRB

C. Completed "Application To Use Human Subjects In Research" form

D. Complete study protocol

1. The form and/or study protocol must address:

    a. Title of the study and summary of the research to be conducted,

    b. Investigator potential financial conflicts of interest,

    c. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),

    d. Any sponsors of the study,

    e. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),

    f. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, pregnant women/fetuses/neonates [i.e., newborns up to 28 days], or handicapped, economically/educationally disadvantaged, or mentally disabled persons), and any special protections provided to these subjects

    g. Study design (including, as needed, a discussion of the appropriateness of research methods),

h. Description of procedures to be performed,
    i. Note: the procedures must include information on differentiation of usual care from research (if appropriate).

i. This applies when the investigator provides for usual care. If the protocol involves "usual care," the protocol must either include a narrative section or there must be a separate document in the IRB application that clearly differentiates the research intervention(s) from "usual care" (whether the "usual care" is limited to one "arm" of the study or is being delivered to all study subjects).

j. When a study involves "usual care," in the protocol or a separate document in the IRB application the investigator must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject's health care provider) responsible for relevant aspects of both the research and the usual care.

k. The subject needs to be able to identify which activity (e.g., treatment or service) is research, and which is usual care, and know who (the researcher or the subject's health care provider) is responsible for:
    i. Explaining potential risks and be benefits of the treatment or service to the subject;
    ii. Providing the treatment or service;
    iii. Monitoring the treatment or service, as applicable;
    iv. Defining whether the adverse events result from usual care or research, as applicable;
    v. Alerting the subject if there is a problem with the treatment or service (e.g., a newly discovered risk, a product recall); and
    vi. Documenting the subject's clinical course while receiving the treatment or service, as applicable.

l. Risk assessment and safety monitoring provisions
    i. For prospective studies involving more than minimal risk, this plan must include, but is not limited to, the following:
        i. What safety information will be collected;
        ii. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects);
        iii. The frequency of data collection including when safety data collection starts;
        iv. The frequency or periodicity of review of cumulative safety data;
        v. If applicable, statistical tests for analyzing the safety data to determine if harm is occurring;
        vi. Provisions for the oversight of safety data; and
        vii. Conditions that trigger an immediate suspension of the research, if applicable.
            a. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations
            b. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Pennsylvania as an individual under the age of 18),

use legally authorized representatives, witnesses, translators and document storage,

c. Any remuneration to subjects for their participation,
d. Any compensation for injured research subjects,
e. Provisions for protection of subject's privacy and data confidentiality
    i. Provisions for Reuse of Data. This means the investigator, if the data may be reused in other studies, describes the research data repository in which the data is to be stored. There must be a research informed consent and a HIPAA authorization associated with the protocol unless these requirements are waived by the IRB. If the IRB does not waive the requirements then the informed consent and HIPAA authorization content must include language on the uses and disclosures of the data as defined in the protocol as well as information on how privacy and confidentiality will be maintained and how the data will be secured. If the creation and operation of the data repository is not included in the data
    ii. collection protocol, there must be a separate IRB-approved protocol for the creation and operation of the data repository.
    iii. Provisions for Future Use of Specimens.
    iv. If specimens are to be retained after the end of the study for future research, information must be included on where the specimens will be retained, who will have access to them, and how long they will be retained. Current applicable institutional and other Federal requirements must be met for handling, use and storage of biologic specimens and data.
f. Extra costs to subjects for their participation in the study,
g. Inclusion/exclusion of women, minorities, and/or children
h. Professional qualifications to do the research (including a description of necessary support services and facilities);

2. Investigator's Brochure (when one exists);
3. The case report form (when one exists);
4. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;
5. Copies of recruiting advertisements and surveys, questionnaires, or other materials provided to subjects;
6. Copies of relevant grant applications (if any);
7. Documentation verifying IND or IDE numbers or status (if appropriate)
    a. Exemption 1. That the research involves:
        i. The drug product is lawfully marketed in the United States.

ii. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
iii. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
iv. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
v. The investigation is conducted in compliance with 21 CFR 50 and 56.
vi. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

b. Exemption 2. That the research is:
   i. A clinical investigation of an in vitro diagnostic biological product that involves one or more of the following:
      i. Blood grouping serum.
      ii. Reagent red blood cells.
      iii. Anti-human globulin.
   ii. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
   iii. The diagnostic test is shipped in compliance with 21 CFR 3 12.160.

c. Exemption 3. That the research is:
   i. A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.
   ii. For device submissions in which no IDE number is provided, in formation must be provided allowing the IRB coordinator or IRB staff to confirm that the devise is one that satisfies one of the following device exemptions:
   iii. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
   iv. A device, other than a transitional device, introduced into commercial distribution on or after
   v. May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of part 807 in determining substantial equivalence.
   vi. A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
      a. Is noninvasive.
      b. Does not require an invasive sampling procedure that presents significant risk.

c. Does not by design or intention in introduce energy into a participant
d. •Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

vii. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

viii. A custom device as defined in 21 CFR 8 12.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

8. For funded studies in which the sponsor (including DHHS/NIH) has approved the human subjects protocol and consent form, submit a copy of these documents

II SUBMISSION OF DOCUMENTS TO THE IRB

A. <u>For protocols involving more than minimal risk (review by the full Institutional Review Board):</u>

a. Submit the completed Application To Use Human Subjects In Research form and supporting documents (must contain original signatures of principal investigator, co-investigator(s) and, for a student PI, the faculty advisor). In addition, submit the research protocol.

B. <u>For protocols involving no more than minimal risk (expedited review by the screening</u>
C. <u>committee):</u>

a. Submit the completed Application To Use Human Subjects In Research form and supporting documents (one copy must contain original signatures of principal investigator, co-investigator(s) and, for a student PI, the faculty advisor).

D. <u>For protocols meeting criteria for exempt research:</u>

a. Submit the completed signed Application To Use Human Subjects In Research form and supporting documents

E. The submission may be signed electronically or manually. The IRB will accept the following as documentation from an investigator:

1. An original, signed signature
2. A pdf file, or photo file of a signature
3. An indication that the signature is electronic (e.g. //es//Name) to indicate that this is Jane's electronic signature
4. A statement that the signature belongs to the investigator (e.g. "I attest that this is my electronic signature")

5. The electronic signature needs to be submitted on the e-mail account of the principal investigator. If the PI wishes to submit the electronic signatures for coinvestigators, this can be done by sending a file as described above from the co-PI under the e-mail of the Principal Investigator (to indicate that this person has approved the coinvestigator's attestation).

F. Protocols must be received by the IRB at least eight working days in advance of the meeting at which they will be reviewed.

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

FILLABLE IRB APPLICATIONS

Harrisburg University of Science and Technology
Institutional Review Board

APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH

For Exempt Studies Only

***IRB ETHICS TRAINING**: The participating Faculty member(s), Graduate Student Researcher(s), and any External Researcher(s) MUST have a valid completion certificate from the CITI Course in Human Subjects Online Training before submitting an IRB application for projects involving human subjects. Include a copy of your CITI Training Completion Certificate with your IRB application if one is not already on file.*

1. PROPOSED DATA COLLECTION DATES: From (MM/DD/YYYY) to (MM/DD/YYYY)
Data collection dates should allow time for the IRB to review your protocol. Please allow at least one (1) week from the date you turn in the application for processing.

2. INVESTIGATOR(S): Copy and paste additional investigator names as needed. *If an undergraduate student project, the faculty advisor should be listed as a Co-Investigator and as the approving faculty advisor).*

Investigator Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

Faculty Advisor Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

For all students, this research is for (*check all that apply*):

☐ Master's Thesis/Project
☐ PhD Dissertation
☐ Undergraduate Project
☐ Independent Study
☐ GRAD695 Course requirement
☐ Other: (describe project here)

3. **PROJECT TITLE**: Click or tap here to enter text.

4. PARTICIPANTS:

a. Number of participants proposed/anticipated: (enter number here)

b. Type(s) of participants:

☐ Children (17 or younger)
☐ Patients in institutions
☐ Prisoners
☐ Pregnant women
☐ Adults (18 years of age or older)
☐ HU students (18 years of age or older)
☐ Faculty or external collaborators
☐ Other: (describe population here)

5. FUNDING:

Are you seeking funding for this project/research? ☐ No ☐ Yes
If yes, submit one copy of the proposal summary or abstract with the application.

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

6. REVIEW CATEGORY: **Please mark all items that apply**.

Note: Research with children or pregnant women often cannot be reviewed under expedited review. Please consult with the IRB Administrator to see if your protocol involving these subjects would require full board review.

Exempt Review (based on the following categories):

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.**

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available **or** if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Less likely types in the exempt category include the following:

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **ADDITIONAL INFORMATION REQUIRED**:

You may insert the required information below in this section OR include it in your submission as separate documents:

a. Project Topic or Research Question(s): Click or tap here to enter text.
b. Explanation of why the data collected is anonymous.
    i. Methodology (the design of the study) Click or tap here to enter text.
    ii. Data Collection (what elements and how you will collect data) *This is often met by including the actual survey form with both the introduction and questions.*

Click or tap here to enter text.

8. **AFFIRMATION OF COMPLIANCE:**

Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Completion. Failure to submit may result in adverse actions IAW IRB Policy. All consent forms and data must be kept at least three years after the study ends.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB) and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

Click or tap here to enter text.

Signature of Investigator (MM/DD/YYYY)
(Written or digital)

HU E-mail Address

Date

Click or tap here to enter text.

Signature of Co-investigator (MM/DD/YYYY)
(Written or digital)

HU E-mail Address

Date

(Cut and Paste additional investigator signature lines as needed).

APPROVAL OF FACULTY ADVISOR OR SPONSOR (if a student project or thesis):

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the HU IRB and have complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

Copy and paste additional faculty advisor approval signatures and contact information lines as needed below.)

Printed Name of Faculty Advisor: Click or tap here to enter text.
Program: Click or tap here to enter text.
Phone: Click or tap here to enter text.
HU E-mail Address: Click or tap here to enter text.

Signature of Faculty Advisor
(Written or digital)

Date (MM/DD/YYYY)

Harrisburg University of Science and Technology
Institutional Review Board

APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH

For Expedited Studies Only

IRB ETHICS TRAINING: The participating Faculty member(s), Graduate Student Researcher(s), and any External Researcher(s) MUST have a valid completion certificate from the CITI Course in Human Subjects Online Training before submitting an IRB application for projects involving human subjects. Include a copy of your CITI Training Completion Certificate with your IRB application if one is not already on file.

1. PROPOSED DATA COLLECTION DATES: From (MM/DD/YYYY) to (MM/DD/YYYY)
Data collection dates should allow time for the IRB to review your protocol. *Please allow at least one (1) week from the date you turn in the application for processing.*

2. INVESTIGATOR(S): Copy and paste additional investigator names as needed. If an undergraduate student project, the faculty advisor should be listed as a Co-Investigator and as the approving faculty advisor).

Investigator Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

Faculty Advisor Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

For all students, this research is for (*check all that apply*):

☐ Master's Thesis/Project
☐ PhD Dissertation
☐ Undergraduate Project
☐ Independent Study
☐ GRAD695 Course requirement
☐ Other: (describe other project here)
☐ Other: (describe other project here)

3. **PROJECT TITLE**: Click or tap here to enter text.

4. PARTICIPANTS:

a. Number of participants proposed/anticipated: (enter number here)

b. Type(s) of participants:

☐ Children (17 or younger) ☐ Adults (18 years of age or older)
☐ Patients in institutions ☐ HU students (18 years of age or older)
☐ Prisoners ☐ Faculty or external collaborators
☐ Pregnant women ☐ Other: (describe population here)

5. FUNDING: Total project period from (MM/DD/YYYY) to (MM/DD/YYYY)

Are you seeking funding for this project/research? ☐ No ☐ Yes
If yes, submit one copy of the proposal summary or abstract with the application.

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

6. REVIEW CATEGORY: **Please mark all items that apply**.

Note: Research with children or pregnant women often cannot be reviewed under expedited review. Please consult with the IRB Administrator to see if your protocol involving these subjects would require full board review.

Expedited Review (based on the following categories):

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if:(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Collection of data from voice, digital, or image recordings made for research purposes

☐ Moderate exercise, muscular strength testing, body composition and flexibility testing from healthy volunteers (excludes x-rays, or microwaves)

☐ Non-manipulative, non-stressful research on individual or group behavior

☐ Collection of biological specimens by noninvasive means

☐ Collection of blood samples by finger prick, heel stick, ear stick or venipuncture

☐ Study of existing data, documents, records, or pathological or diagnostic specimens

7. **ATTACHMENTS OR TEXT ENTRY REQUIRED**:

a. Project or Research Question(s): Click or tap here to enter text.
b. Methodology (the design of the study): Click or tap here to enter text.
c. Data Collection (who, what, when, where, and how you will collect data)
   i. Explanation of how the collected data will be extracted, stored, and archived/destroyed to assure confidentiality and blinding of anyone participating in its analysis: Click or tap here to enter text.
   ii. Explanation of why the personally identifiable data collected is necessary to answer your question(s): Click or tap here to enter text.

8. **CONFIDENTIALITY OF DATA**: Include the confidentiality of data section below: Click or tap here to enter text.

Please delete the instructions below when complete.
Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting, etc.) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed. If not possible, state why. Again, this is the how, what, when, where, and how you will store and secure the data you have collected. If collecting your data through interviews or focus groups be specific as to the type of recordings (i.e., audio, video, photograph) and type of recording devices used (i.e., analog or digital). If transferring from analog (tape recordings) how will you transcribe the data and what will you do with the tape recordings after transcription. Also include how will you destroy the tape recording after transcription (i.e., demagnetize, shred, etc…). If digital recordings will you be transferring the data from the digital recording device to a computer and what will be done with the data in the digital recording device after you have downloaded the data to the computer (i.e., data will be erased, deleted, etc…).

9. **INFORMED CONSENT**:

Informed consent is usually written; however, in some circumstances it may be oral or electronic in nature. Waivers of informed consent may be granted under certain limited conditions, and any request for such should include explicit justification. Remember that the informed consent should be unique to each study being proposed and should also be written at the 7th grade reading level or lower if needed. (An example of an informed consent format is provided on the IRB website though you do not have to follow this example, but it must include the below items a through i).

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like the written consent document, they should include:

a. Identification of the researcher(s)
b. The nature and purpose of the study
c. Expected duration of participant involvement
d. How confidentiality or anonymity will be maintained
e. The voluntary nature of participation
f. Participants' right to withdraw at any time without penalty
g. Information about foreseeable risks and benefits (or none)
h. Contact information for questions or additional information
i. First paragraph should have a statement that the research has been approved by the Institutional Review Board of Harrisburg University of Science and Technology

A copy of the Informed Consent or text for oral consent must be provided to the IRB. For non-English-speaking participants, be sure to include an accurate translation.

10. **DEBRIEFING STATEMENT**:

A debriefing statement is usually *required only if any type of deception is used* in the study. Participants may also be debriefed about their behavioral response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influences the study may have on participants should be minimized or eliminated.

The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study, and contact information for additional details or answers to questions. Any potential predictions about study outcomes should be non-directional. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. Note that debriefing is normally only used when deception is utilized in the research otherwise it does not need to be included. If you are a student researcher, please check with your faculty advisor on whether you should include a debriefing statement.

Also, some researchers use an information form at the end to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma. You may include an information or emergency contact form (so titled) if needed but please refer to your faculty advisor if you are a student researcher.

11. **AFFIRMATION OF COMPLIANCE:**

Note: Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Ending by emailing the IRB Chair. Failure to submit may result in adverse actions IAW IRB Policy All consent forms and data must be kept at least three years after the study ends.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB) and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

Signature of Investigator HU E-mail Address Date

Signature of Co-investigator HU E-mail Address Date

(Cut and Paste additional investigator signature lines as needed).

APPROVAL OF FACULTY ADVISOR OR SPONSOR:

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the HU IRB and have complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

(Copy and paste additional faculty advisor approval signatures and contact information lines as needed below.)

Printed Name of Faculty Advisor: Click or tap here to enter text.
Program: Click or tap here to enter text.
Phone: Click or tap here to enter text.
HU E-mail Address: Click or tap here to enter text.

Signature of Faculty Advisor Date

Harrisburg University of Science and Technology
Institutional Review Board

APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH
For FULL BOARD APPROVAL ONLY

Full Board Review: Involves vulnerable populations including children, prisoners, pregnant women, challenged persons OR more than minimal risk to subjects.

***IRB ETHICS TRAINING**: The participating Faculty member(s), Graduate Student Researcher(s), and any External Researcher(s) MUST have a valid completion certificate from the CITI Course in Human Subjects Online Training before submitting an IRB application for projects involving human subjects. Include a copy of your CITI Training Completion Certificate with your IRB application if one is not already on file. Certificates are valid for 3 years.*

Training is available at: citiprogram.org using your HU email address to register.

APPLICATION STATUS: ☐ New submission ☐ Resubmission with revisions [IRB No.]

1. **PROPOSED DATA COLLECTION DATES**: From (MM/DD/YYYY) to (MM/DD/YYYY)
Data collection dates should allow time for the IRB to review your protocol. Please allow at least three (3) months from the date you turn in this application for processing unless approved for special handling by the IRB Chair.

2. **INVESTIGATOR(S):** *Copy and paste additional investigator names as needed. If an undergraduate student project, the faculty advisor should be listed as a Co-Investigator and as the approving faculty advisor).*

Investigator Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

Faculty Advisor Name: Click or tap here to enter text.
Program: Click or tap here to enter text.
Email: Click or tap here to enter text.

For all students, this research is for (*check all that apply*):

☐ Master's Thesis/Project ☐ Independent Study
☐ PhD Dissertation ☐ GRAD695 Course requirement
☐ Undergraduate Project ☐ Other: (describe other study here)

3. **PROJECT TITLE**: Click or tap here to enter text.

4. **PARTICIPANTS:**

a. Number of participants proposed/anticipated: (click to enter number here)
Please enter or attach your power analysis to justify your sample size.

b. Proposed participant genders included in the study:

☐ Female only ☐ Male only ☐ All genders

c. Type(s) of participants:

☐ Children (17 or younger) ☐ Adults (18 years of age or older)
☐ Patients in institutions ☐ HU students (18 years of age or older)
☐ Prisoners ☐ Faculty or external collaborators
☐ Pregnant women ☐ Adults with diminished capacity
☐ Economically disadvantaged ☐ Adults with limited language skills
☐ Other: (describe population here)

Attach or enter justification for use of any persons from vulnerable populations.
If using HU staff, stakeholders or students, indicate protocols for avoiding conflict of interest and coercion. Researcher convenience is not sufficient justification.
:Click or tap here to enter text.

5. **FUNDING:**

Are you seeking funding for this project/research? ☐ No ☐ Yes

If yes, submit one copy of the proposal summary or abstract with the application.
If yes, enter the total project period: From (MM/DD/YYYY) to (MM/DD/YYYY)
If yes, affirm there is no conflict of interest ☐ *Provide documentation of COI training if required by funding source*

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant form and instructions from funding source with this application.

Is this study a collaborative research project with other US Institutions that relies on a single IRB of record? ☐ No ☐ Yes ☐ N/A

6. **SUBMIT ALL RELEVANT PROJECT MATERIALS AND DOCUMENTS: Attach the following materials/documents:**

SURVEYS, QUESTIONNAIRES, INTERVIEW SCRIPTS OR MEASUREMENT INSTRUMENTS

LETTERS OF APPROVAL, COLLABORATION, OR SITE PERMISSION, AS APPLICABLE

RECRUITMENT OF PARTICIPANTS (required):

Attach or enter your 'recruitment of participants' section below:
Click or tap here to enter text.

Please delete the instructions below when section is complete.

b. Describe sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Include all relevant characteristics with regard to age, ethnicity, sex, institutional status (i.e., patients or prisoners), and general state of physical and mental health. Include any Inclusion/exclusion criteria.

c. Participant recruitment materials (fliers, advertisements, etc.)

Note: Recruitment issues can be especially critical when any federally defined "vulnerable population" is involved. This includes children, pregnant women, prisoners, others who are institutionalized, and anyone who might be at particular risk or whose cooperation might be dependent on coercions, no matter how slight.

DESCRIPTION OF THE PROJECT (required):

Attach or enter your 'description of the project' section below:
Click or tap here to enter text.

Please delete the instructions below when section is complete.
Briefly describe the objectives and methodology of your research (including hypothesis and/or research questions), data collection procedures, and features of the research design that involve specific procedures or special conditions for participants (including frequency, duration, and location of participation.

Include your project description first before proceeding to the subheadings below (Project Description should be from 3 paragraphs to 1 page in length)

It would be most helpful to organize this section with the following sub-headings:

d. Objectives of the Study
e. Hypothesis or Research Questions
f. Methodology (the design of the study)
g. Data Collection (the who, what, when, where, and how you will collect the data)

h. Procedures involving subjects, if applicable
i. Special conditions or anticipated problems or risks, if applicable
j. Dissemination (how will you present and publish your research: this includes presenting at a conference, publishing in a journal, thesis, or dissertation, etc.)

CONFIDENTIALITY OF DATA (required):

Attach or enter your 'confidentiality of data' section below:
Click or tap here to enter text.

Please delete the instructions below when section is complete.
Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting, etc.) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed. If not possible, state why. Again, this is the how, what, when, where, and how you will store and secure the data you have collected. If collecting your data through interviews or focus groups be specific as to the type of recordings (i.e., audio, video, photograph) and type of recording devices used (i.e., analog or digital). If transferring from analog (tape recordings) how will you transcribe the data and what will you do with the tape recordings after transcription. Also include how will you destroy the tape recording after transcription (i.e., demagnetize, shred, etc.). If digital recordings will you be transferring the data from the digital recording device to a computer and what will be done with the data in the digital recording device after you have downloaded the data to the computer (i.e., data will be erased, deleted, etc.).

RISKS AND BENEFITS (required):

Attach or enter your 'risk and benefits' section below:
Click or tap here to enter text.

Please delete the instructions below when section is complete.
Describe in detail any immediate, short-term, or long-range risks that may arise for participants as a result of procedures associated with your study. Risks may be physical, psychological, social, legal, or economic; they would include side effects, risks of placebo, delay in customary treatment, etc. Indicate any precautions that will be taken to minimize risks. Also indicate any anticipated benefits to participants and/or society from the knowledge that may reasonably be expected to result from the study. Risks and benefits MUST BE included in the protocol and in the informed consent document.

INFORMED CONSENT (required):
Informed Consent templates are available in this forms folder and on the HU IRB webpage.
Attach or enter your 'Informed Consent' section below:
Click or tap here to enter text.

Please delete the instructions below when section is complete.
Informed consent is usually written; however, in some circumstances it may be oral or electronic in nature. Waivers of informed consent may be granted under certain limited conditions, and any request for such should include explicit justification. Remember that the informed consent should be unique to each study being proposed and should also be written at the 7th grade reading level or lower if needed. (An example of an informed consent format is provided on the IRB website though you do not have to follow this example, but it must include the below items a through i).

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like the written consent document, they should include:

j. Identification of the researcher(s)
k. The nature and purpose of the study
l. Expected duration of participant involvement
m. How confidentiality or anonymity will be maintained
n. The voluntary nature of participation
o. Participants' right to withdraw at any time without penalty
p. Information about foreseeable risks and benefits (or none)
q. Contact information for questions or additional information
r. First paragraph should have a statement that the research has been approved by the Institutional Review Board of Harrisburg University of Science and Technology

A copy of the Informed Consent or text for oral consent must be provided to the IRB.

For non-English-speaking participants, be sure to include an accurate translation.

CHILD ASSENT (if applicable):
A Child Assent template for Full Board Review studies is available on the IRB webpage. Attach or enter your 'child assent' section below:
Click or tap here to enter text.

"Assent" is defined by the regulations as follows: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (See federal regulation at 45 CFR 46.402 (b)) and OHRP questions and answers at http://answers.hhs.gov/ohrp/questions/7202)

This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all the children to be involved in a proposed research activity, or on an individual basis.

DEBRIEFING STATEMENT (if applicable):

Attach or enter your 'debriefing statement' section below:
Click or tap here to enter text.

A debriefing statement is usually required only if any type of deception or psychological effects are used in the study. Participants may also be debriefed about their behavioral response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influences the study may have on participants should be minimized or eliminated.

The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study, and contact information for additional details or answers to questions. Any potential predictions about study outcomes should be non-directional. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. Note that debriefing is normally only used when deception is utilized in the research otherwise it does not need to be included. If you are a student researcher, please check with your faculty advisor on whether you should include a debriefing statement.

Also, some researchers use an information form at the end to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma. You may include an information or emergency contact form (so titled) if needed but please refer to your faculty advisor if you are a student researcher.

7. AFFIRMATION OF COMPLIANCE (required):

Note: Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Ending by emailing the IRB Chair. Failure to submit may result in adverse actions per IRB Policy. All consent forms and data must be kept at least three years after the study ends.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB) and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

Signature of Investigator: Date: Click or tap to enter a date.
(written or digital)
Program: Click or tap here to enter text.
HU E-mail Address: Click or tap here to enter text.

Signature of Co-investigator Date: Click or tap to enter a date.
(written or digital)
Program: Click or tap here to enter text.
HU E-mail Address: Click or tap here to enter text.

(Cut and Paste additional investigator signature lines as needed).

APPROVAL OF FACULTY ADVISOR OR SPONSOR:

I affirm that I have proofread and reviewed the accuracy of this application and accept responsibility for the ethical conduct of research, supervision of any students, and documentation maintenance.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the HU IRB and have complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.

Printed Name of Faculty Advisor: Click or tap here to enter text.
Program: Click or tap here to enter text.
Phone: Click or tap here to enter text.
HU E-mail Address: Click or tap here to enter text.

Signature of Faculty Advisor
(written or digital)

Date: Click or tap to enter a date.

APPROVAL OF LICENSED PHYSICIAN (if applicable):

*This signature is **required only if the project involves medical procedures** and neither the investigator nor the faculty advisor is a licensed physician.*

Printed Name of Physician: Click or tap here to enter text.
E-mail Address: Click or tap here to enter text.
Phone: Click or tap here to enter text.

Signature of Physician
(written or digital)

Date: Click or tap to enter a date.

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

REVIEW OF HUMAN SUBJECTS RESEARCH

I POLICY

A. All research at the university involving human subjects shall be submitted to the IRB for review and must be reviewed at a convened meeting of the HU IRB unless the IRB determines the research qualifies for expedited review or exempt status.

B. The role of the IRB is to protect participants in human subjects' research by assuring that the risks of research are proportionate to the value to the subjects involved in the research, that the research is ethical, and that it is conducted in accordance with the principles of the Belmont Report and federal, state, and local laws and regulations. See:

• http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (the Common rule governing federally funded research)

• http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm (the Belmont Report)

• http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html (FDA Regulations governing the protection of human subjects)

• http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr56_02.html (FDA Regulations governing Institutional Review Boards)

• http://www.fda.gov/cdrh/devadvice/ide/index.shtml (FDA Regulations governing clinical trials and investigational devices)

• http://www.fda.gov/cder/guidance/index.htm (FDA Guidance Documents)

II DEFINITIONS

A. The IRB shall use the following definitions to determine whether an activity shall qualify as human subjects' research requiring IRB review and approval. IRB staff will refer any questions about whether a proposed study qualifies as human subject research to the IRB chair, who will make a determination using the criteria listed below:

As used herein, A *human subject* is an individual on whose specimen an investigational device is used.

B. Human Subjects Research shall include all activities which either:

1. Meet the Department of Health and Human Services' definition of 'research' as any 'systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge' and which involve person(s) who qualify as 'human subjects' within the meaning of relevant regulations (45 CFR 46.102.d) as any 'living individual about whom an investigator conducting research obtains (i) data through intervention

or interaction with the individual, or (ii) identifiable private information, or data from which the identity of the subject is or may readily be ascertained by the investigator.' (45 CFR46.102(f)).

Thus, to meet the definition of research with human subjects, one or both of the following must be true:

a. The researcher is conducting a pilot study, a preliminary study, or other preliminary research.

b. The researcher has designed a study to collect information in a systematic way with the intention of contributing to a field of knowledge. (This does not mean that the study needs to be replicable, but rather that there is an intent to develop or contribute to a field of knowledge in a manner consistent with your discipline.)

And the researcher must be:

1. Interacting with living human beings in order to gather data about them, using methods such as interviews, focus groups, questionnaires, and participant observation, or

2. Conducting interventions with living human beings such as experiments and manipulations of subjects or subjects' environments, or

3. Observing or recording private behavior (behavior that individuals have a reasonable expectation will not be observed and recorded), or

4. Obtaining private identifiable information that has been collected about or provided by individuals, such as a school record or identifiable information collected by another researcher or organization.

C. Examples of Studies That May Not Meet the Definition

- Analysis of de-identified data
- Expert consultation

Key words in the definition of a human subject are "a living individual about whom" a researcher obtains information. Some interactions with people for the purpose of collecting information do not any collect information about that person. For example, a researcher may contact a non-governmental organization to ask about its sources of funding.

• Program evaluations and quality improvement studies

Not every study is designed to contribute to a field of knowledge. For example, if data are being collected to improve a program within an institution and will be used only for that purpose, the collection of that information would not constitute research with human subjects.

• Classroom research

In classes teaching research methods such as fieldwork, statistical analysis, or interview techniques, students may be assigned to conduct interviews, distribute questionnaires, or engage in participant observation. If the purpose of these activities is solely pedagogical and they are not

designed to contribute to a body of knowledge, the activities do not meet the definition of research with human subjects.

-OR-

2. Qualify under the Food and Drug Administration regulations as an "Investigational use" involving any use of an approved product in the context of a clinical study protocol (21 CFR 312.3(b)) and which involves one or more "human subjects" as defined in relevant regulations as individual(s) who are or become participant(s) in research, either as recipient(s) of a test article or as a control. A subject may be either a healthy human or a patient (21 CFR 56.102(e); 812.3(p)).

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (for example, a medical record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects (i.e., the identify of the subject is or may readily be ascertained by the investigator.

Research activities subject to this policy shall include clinical investigations, defined as any experiment that involves a test article and one or more human participants and that is one of the following:

- o Subject to the requirements for prior submission to the FDA, or
- o Not subject to the requirements for prior submission to FDA, but the results of which are intended to be submitted later to, or held for inspection by the FDA as part of an application for a research marketing permit.

Clinical Investigations may be regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, including any use of a drug, other than the use of an approved drug in the course of medical practice, and clinical investigations regulated by the Food and Drug Administration under section 520(g) of the Act, including any use of a medical device, other than the use of an approved medical device in the course of medical practice.

The decision chart from the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services attached to the end of this procedure can be helpful in determining whether a research proposal involves "human subjects" as defined in the HHS regulations (45 CFR 46_Common Rule). Protocols submitted to the IRB will be reviewed and the determination made if the proposed activity constitutes research involving human participants. If this is in the affirmative, the protocol will be reviewed and the results communicated to the investigator in the minutes of the IRB meeting. If the protocol is found to

not constitute research involving human participants, the investigator will be notified by mail of this finding.

If the IRB receives a protocol for review after a human subjects research study has been completed, without prior IRB approval, the protocol will not be reviewed. The Investigator will be notified of the regulatory requirements requiring prospective IRB approval of human subjects research. The Investigator will be informed that the data may not be used for any publications, presentations, thesis, or dissertation requirements.

III APPLICABILITY

1. This policy shall apply to all human subjects' research:

    a. Sponsored by the University (unless the research is conducted at another institution with which HU has an "IRB Authorization Agreement"; or

    b. Conducted by or under the direction of any University employee or agent of the University in connection with his/her institutional responsibilities (unless the research is conducted at another institution with which HU has an "IRB Authorization Agreement"); or

    c. Conducted by or under the direction of any University employee or agent of the University using any University property or facility; or

    d. Involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects.

2. Cooperative activities

    a. Cooperative activities relating to human subjects are those which involve HU and another institution. Normally the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

        i. Both institutions have Federalwide Assurances (FWAs) approved by OHRP

        ii. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

        iii.The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

    b. In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research, and submit documentation of such approvals to the other IRBs. The IRB Coordinator will verify (via the OHRP website) that the other institution(s) has/have approved FWAs.

3. Material reviewed by the IRB

    a. New protocols

i. A copy of the Application To Use Human Subjects In Research, summary of research, and all informed consent documents (including any advertisement/recruiting materials) are provided to all members of the IRB prior to each meeting for their review. Copies of all material submitted by the investigator are available to any IRB member upon request.

ii. Primary reviewers (3 per each new protocol) receive copies of all materials submitted. These include (as applicable):

1. The Application To Use Human Subjects In Research form
2. The Study Protocol
3. C.V. of the Primary Investigator
4. Sponsor's brochure (if applicable)
5. The Grant Application (if applicable)
6. Informed consent document(s)
7. Study Materials for Subjects (i.e. questionnaires, surveys; if applicable)
8. Advertising Copy (if applicable)
9. DHHS-approved sample consent document (if applicable)
10. DHHS-approved protocol (if applicable)
11. Previous reviewer's comments and investigator's responses (if applicable)

b. Modifications of previously approved protocols

i. All members of the committee are provided with a copy of the amendment, supportive materials submitted explaining or justifying the amendment, and, if appropriate, the consent document with any revisions clearly indicated.

ii. Copies of all materials initially submitted for approval of the research are available to any committee member if requested.

c. Continuing review of protocols

i. All members of the committee are provided with a completed continuing review questionnaire, a summary of previous protocol activities and future project plans, and copies of all Informed Consent documents, surveys and/or questionnaires currently being used.

ii. Copies of all material initially submitted for approval of the research are available to any committee member if requested.

IV CRITERIA FOR APPROVAL BY THE IRB

In order to approve human subject's research covered by this policy, the IRB shall determine human research requirements are satisfied. For FDA-regulated research, FDA regulatory requirements must also be met. The IRB has the final authority to decide whether requirements have been met, to identify steps that must be taken to meet requirements, and to approve or disapprove the research. These requirements include:

1. Risks to participants are minimized:

a. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and

b. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

c. The PI must provide a plan for data safety monitoring in any situation in which participants might be at greater than minimal risk of harm, including when a drug or device is being tested for safety or effectiveness for marketing approval or in placebo-controlled trials or when marketed drugs are being tested for another indication or compared for safety or effectiveness. The level of detail in the plan should be based on the degree of risk to research participants. Low risk studies, for example, may have simple plans. Multi-center trials generally have Data Safety Monitoring boards (DSMB). Safety Monitoring plans, including plans for DSMBs, should:

a. Describe how risks are minimized and how they are reasonable in relation to anticipated benefits to participants
b. Describe the data required to be reported and monitored
c. Describe how the data is to be reported, including a plan to assure reporting of adverse events and unanticipated problems involving risk to participants or others
d. List procedures for analysis and interpretation of data
e. Describe the frequency of monitoring. The IRB will evaluate the frequency of data review, whether after a specific length of time or after a specific number of participants are enrolled, based on the likelihood or magnitude of risks to participants
f. Describe how or by whom the data will be reviewed. The IRB will evaluate whether the method is appropriate based on the size and complexity of the research and magnitude of risk to participants. Most large multicenter trials have DSMBs. Smaller trials could have monitoring committees, an independent medical monitor or other investigator, or if there is no other monitoring individual or committee, the IRB can request periodic data or safety monitoring.
g. Describe any proposed actions to be taken for specific events that may be anticipated, i.e., unexpected toxicities of drugs or greater than anticipated side effects
h. Describe the data and safety information that will be provided to the IRB and the frequency with which it will be reported

i. Specify whether serious adverse events will be promptly reported to and evaluated by a data safety and monitoring process

2. Scientific or Scholarly Review by qualified individuals(s) has demonstrated that (a) the research uses procedures which are consistent with sound research design; (b) the research design is likely to answer the proposed scientific question, and (3) the importance of the knowledge expected to result justifies approval of the research. In addition, the IRB should determine if the investigator has sufficient time to conduct and complete the research and that the investigator has adequate staff and other resources, including facilities, to conduct the research.

3. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

4. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly aware of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, and others, as designated by the IRB.

5. The investigator (or spouse or dependent children) or other person(s) responsible for the research do not have financial interests which may be a perceived or real conflict of interest. These include:

a. A vested interest in any actual or potential commercial enterprise/business associated with any aspect of the protocol (other than patents)

b. Equity interests in the sponsor of this study whose value, when aggregated for the immediate family, is greater than $10,000, **or** ownership, stock options or other financial interest related to the research of any value whose value can not be determined through reference to publicly available prices

c. Payment by the sponsor greater than $10,000 to the investigator's performing organization(s) exclusive of the costs of conducting the study Ownership interest, stock options or other financial interest related to the research whose value, when aggregated for the immediate family, represents >5% interest in any single entity.

d. Compensation related to the research whose amount is affected by the outcome of the research

e. Board or executive relationship related to the research, regardless of compensation

i. Direct payment by the sponsor to the investigator(s), their spouses or dependent children

ii. Financial interest (other than patents) in non-sponsored research

6. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CRF 50.20, the law of the state where the research is conducted, and as required by University policy.

7. When investigators need to obtain consent from the legally authorized representative of an adult subject (i.e. to conduct essential research on problems that are unique to persons who are incompetent or who have an impaired decision-making capacity), such consent will be obtained from one of the following:

a. A health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document

b. A court-appointed guardian of the person

Such consent shall be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.

Should participants become competent during the duration of the study, their consent to continue in the research should be obtained when possible.

8. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CRF 50.20, with the law of the state where the research is conducted, and in accordance with and to the extent required by University policy.

9. When appropriate, the protocol makes adequate provision for monitoring the data collected to ensure the safety of participants.

10. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. This includes assuring that only private information essential to the research is collected; that the circumstances in which private information is collected are conducive to privacy; and that this information is maintained in a secure environment. When protected health information (PHI) is being collected, there must be documentation that authorization under the Health Insurance Portability Authorization Act (HIPAA) is to be obtained. If a waiver of this documentation is sought, the IRB must ascertain and document that the criteria for waiver have been met.

11. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

12. Payments are appropriate as described below:

a. The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence.

b. Credit for payment accruing as the study progresses is not contingent upon the participant completing the entire study.

c. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study

V EXPIRATION OF APPROVAL

Approval for new research will be granted for a period of up to one year minus one day from the date on which the protocol was initially approved. A shorter time may be specified based on the recommendation of the IRB. Reasons for a shorter period for review may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to participants, projects involving vulnerable populations, and projects conducted by a P.I. who has previously failed to comply with IRB requirements. If restrictions have been placed on a protocol which require response or action from an investigator, the date of approval remains that of the meeting at which the protocol was approved (with restrictions) and not the date that the restrictions were met.

VI CONTINUING REVIEW

The IRB will conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. The degree of risk, the inclusion of any vulnerable populations, occurrence of problems with the research, and determination of noncompliance will all be taken into consideration when determining the length of the interval for continuing review. Individuals as specified for vulnerable populations will be in attendance at any meeting where research involves vulnerable participants. The process for Continuing Review is completely described in a separate procedure.

VII CONSULTANTS

When the IRB or the IRB chair determines that there is not at least one member with sufficient expertise among the membership to review a human subjects research protocol, the IRB chair must obtain an individual or individuals with appropriate expertise review and comment on the human subjects research. The consultation may be by telephone conference at a convened meeting, by written opinion, or by attendance at a meeting. If the consultant has been asked to review a full board protocol, the consultant may be asked to be available to answer questions at a convened meeting but will be excused from the meeting for vote on the human subjects' research. The consultant will not be counted for purposes of a quorum and may not vote on the human subject's research. For expedited research, a consultant will be asked to give a verbal or written report to the screening committee. The committee will take this report into consideration in making a recommendation regarding the protocol, including possible referral to a convened meeting of the IRB.

If the appropriate expert is not available among the faculty of the university, an individual with the required expertise will be identified in the community, or if no one is available, within another community or academic institution.

Consultants will be asked to comply with the Conflict of Interest Guidelines for IRB members.

VIII CONTINGENT APPROVALS AND SUBSTANTIVE MODIFICATIONS

The IRB may approve the study dependent upon minor wording changes as specified by the IRB or standard language as previously approved by the IRB. The IRB will specify that the IRB Chair or other IRB member will review the changes submitted by the researcher. If the changes conform to the specification of the IRB as reported in the meeting minutes, the designated reviewer will authorize the release of the approval letter. The IRB will be informed of the approval. If the designated reviewer determines hat the changes do not correspond exactly with the requirements of the IRB, the research will be reviewed again by the IRB to determine whether it will be approved.

When the convened IRB requests substantive modifications or clarifications that are directly relevant to the regulatory criteria for approval, the response must be returned to the convened IRB for review and approval.

IX FURTHER APPROVALS

Human subject research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the University.

However, those officials may not approve the human subjects research if it has not been approved by an IRB.

X DOCUMENTATION

The minutes of the IRB meetings document separate deliberations, actions, and votes for each protocol under regular review. Within 21 days of the IRB meeting, the minutes of the meeting will be available for review. Minutes will be approved at a convened IRB meeting. The approved minutes will also be distributed to the Provost.

XI APPLICABLE REGULATIONS:

45 CFR 46.107-109

21 CFR 56.103, 107-109

45 CFR 46 et seq.

45 CFR 164.501

21 CFR 50.3(g)

21 CFR 56.102(e)

21 CFR 312.3(b)

21 C.F.R 812.3(p)

Note: examples of investigations that would NOT be considered to be subject to IRB review include:

1. Research involving deceased persons (e.g. autopsy studies)

2. Research involving insufficient data to provide generalizable knowledge.

Examples:

a. Patient case reports involving 3 or fewer cases

b. Interviews with a single subject for an oral history, or with multiple subjects provided that the purpose of the histories is not to draw conclusions, inform policy, or generalize findings. When doubt exists about whether a proposed project meets the definition of human subject research, the Institutional Review Board (via Research and Sponsored Programs) should be consulted.

GUIDANCE FOR CHAIR OF IRB WHEN CONDUCTING MEETING:

I. Questions to Ask with Each Protocol Reviewed:

1. Length of time recommended for next review?

2. Who will be required to review if revisions have been requested?

3. Are there any vulnerable populations to be enrolled?

If yes, see below to answer required questions/ensure that criteria have been met.

4. Was any waiver of all or part of the elements of informed consent made (these questions must also be asked any time deception is used)? If yes, review the criteria for granting waiver to ensure that all have been met:

a. The research involves no more than minimal risk to the participants;

b. The waiver or alteration will not adversely affect the rights and welfare of the participants;

c. The research could not practicably be carried out without the waiver or alteration;

d. The research is not subject to FDA regulation.

e. That if deception is used, the subjects will be debriefed after participation

f. That for any person for whom consent has not been obtained, whenever appropriate, additional pertinent information will be provided after participation

5. Has a waiver of informed consent documentation been requested? This can be waived only if the one of the following two criteria are met:

a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

5. Has a waiver or request for alteration of the Privacy Rule been requested? This may be appropriate in certain cases (e.g. if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be impracticable to conduct the research). The IRB can waive or partially waive the Authorization (e.g. HIPAA authorization) only if all the following criteria have been met (note: this must be documented in the minutes):

a. The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy

those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule

b. The research could not practicably be conducted without the requested waiver or alteration

c. The research could not practicably be conducted without access to the PHI.

The IRB must specifically describe the PHI for which use or access has been determined to be necessary in connection with the specific research activity.

II. Questions to answer with reported Adverse Events

1. Was the event serious, unanticipated, or research related?

2. Are we satisfied with the description and reporting of the AE, and the action taken by the PI?

3. Are there additional risks that need to be included in the risk section of the consent form?

4. Is there a real or potential increase in risks indicating a need to halt enrollment, close the study, or modify the study design?

5. Do we need an outside expert to review or comment?

6. Is the study a VA study, where VA-specific reporting must occur (if the event was serious, unanticipated and research-related)

III. Questions to ask with any reported unanticipated problems

1. Does the problem involve noncompliance?

Note*: Noncompliance* is defined as the failure to follow the federal regulations governing human subject protection requirements (e.g., 45 CFR 46, 21 CFR 50, 21 CFR 56) or the requirements and determinations of the IRB.

Serious noncompliance is defined as one or more of the following:

• Harm to research subjects

• Exposure of research subjects to a significant risk of substantive harm

• Compromised privacy and confidentiality of the subjects

• Damage caused to the scientific integrity of the data collected

• Willful or knowing misconduct on the part of the investigator

• An adverse impact on ethical principles

Continuing noncompliance is defined as willful, repeated noncompliance by an individual investigator either on a single protocol or multiple protocols.

Examples of noncompliant activities include:

• Conducting research without IRB approval (i.e., before approval obtained, after research expires, without IRB approval)

• Non-use or mis-use of consent forms (i.e., consent not obtained, wrong consent form used)

• Failure to follow approved protocol

• Changing protocol without IRB approval

• Failure to report unanticipated problems or serious adverse events

• Failure to maintain adequate records

• Inadequate training of investigators or research staff

• Other failure to follow university polices and federal regulations

2. Does the problem involve a risk to participants or others?

3. Is the problem serious, or is it continuing in nature?

a. If the answer to any of questions 1-3 is "yes" did the investigator take appropriate action?

b. If not, what further action is required?

IV. Questions to be asked with items submitted for information:

1. Do any of these items indicate that there is an increased risk to the subjects based on the information supplied?

2. If so, what action should be taken with respect to this information?

V. Questions to be asked with vulnerable populations:

Ensure that all the appropriate questions/requirements in the following sections have been answered/met.

1. Did a person experienced with the population review the protocol?

2. For research with incompetent individuals and individuals with impaired decision making capacity, were all the following conditions met?

a. The research can only be carried out by including subjects who are incompetent or with impaired decision-making capacity

b. The research entails no significant risks, tangible or intangible, or if risk is present, there is a greater possibility of direct benefit to the participant

c. There are procedures in place to ensure that the participants legally authorized representative are well informed about their role and obligations to protect the subject

i. The representative will be given descriptions of both the research and their obligations to the subject

ii. The representatives will be told that their obligation is to try and determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in he subject's best interest

d. An option to reconsent is give to any subject who becomes competent during the study

e. There is acknowledgement that if an incompetent subject resists participation, he/she cannot be forced or coerced to participate.

5. For research with minors:

§46.404 Research not involving greater than minimal risk.

Were adequate provisions made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408?.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Were **all** of the following criteria met?

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Were **all** of the following criteria met?

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Refer to regulations. It would be highly unusual for us to be involved in this sort of research.

§46.408 Requirements for permission by parents or guardians and for assent by children.

1. Are the children able to provide assent?

2. Were adequate provisions made for soliciting the assent of the children (if appropriate)

3. Will the permission of both parents or the guardian be sought? (note: one parent can give permission if the other parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the care and custody of the child

4. Have the conditions for how assent will be documented be described, and are these adequate?

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW BY THE IRB

I. GENERAL

A. The IRB conducts continuing review (renewal) of research taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year, and has the authority to observe or have a third party observe the consent process and the research. "Not less than once per year" means that the research must be reviewed before the one-year anniversary of the previous IRB review date, even though the research activity may not have begun until some time after the IRB gave its approval. IRB approval may be withdrawn at any time if warranted by the conduct of the research.

B. The regulations authorize the IRB to establish procedures for the conduct of the research. The regulations authorize the IRB to establish procedures for the concurrent monitoring of research activities involving human subjects. Periodic review of all human research activities is necessary to determine (1) whether the risk/benefit ratio has changed, (2) whether there are unanticipated findings involving risks to subjects, and (3) whether any new information regarding the risks and benefits should be provided to subjects. Continuing review must occur as long as the research remains active for long-term follow-up of participants, even if the research is permanently closed to the enrollment of new participants, and participants have completed research-related interventions. With each continuing review, the IRB will determine whether approval should be continued or withdrawn, and will decide on the frequency of continuing review for each study protocol.

C. IRB approval for the conduct of a study may be withdrawn if the risks to the subjects are determined to be unreasonably high, (for example, more than an expected number of adverse events, unexpected serious adverse events, or evidence that the Investigator is not conducting the investigation in compliance with IRB or Institutional guidelines). Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the study terminated. Continuing review may include, but may not be limited to review of the following:

- Serious, Unexpected Adverse Events, Unanticipated Events
- Non-Compliance
- Amendments
- Significant New Findings
- Interim Results

II. APPLICABILITY

A. The IRB chair and the IRB members at a convened meeting are responsible for review and consideration of approval of protocols during continuing review

1. Continuing review of protocols originally approved by the full board will continue to be performed by the full board.
2. Continuing review of protocols originally approved by expedited review will continue to be reviewed by expedited review. These may be referred to the full committee if it is found that the research activities no longer meet the expedited criteria for review and approval (e.g. are now more than minimal risk).

III. INTERVAL FOR REVIEW FOR PURPOSES OF RENEWAL

The IRB must conduct continuing review of protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk that is determined at the initial review, but not less than once per year. Investigators or qualified designees are required to submit a periodic report prior to the expiration of the study or as specified by the IRB, but at least annually.

Expiration and Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If a complete Progress Report is not received as scheduled, the IRB approval expires and the Investigator must stop all research procedures, recruitment, enrollment, interventions, data collection, and data analysis. The termination must be reported to the project sponsor (if applicable). This will be communicated to the investigator in a letter from the IRB. Once a study has expired, IRB re-review and re-approval must occur before the study can resume. The IRB cannot retrospectively grant approval to cover a period of lapsed IRB approval.

Investigators who believe that currently enrolled participant(s) will be at risk if the research project is discontinued must immediately submit to the IRB Chair a list of participants for whom suspension or termination of the research would cause harm. The IRB Chair or an experienced IRB member designated by the IRB Chair will make the final determination whether it is in the best interest of individual participants to continue to take part in the research interventions or interactions. At the discretion of the reviewers, the matter might be brought to a convened meeting. However, new participants cannot be enrolled, prospective research data cannot be collected, and no procedures that are only being performed for the purpose of the protocol may be performed until the research is again reviewed and approved by the IRB.

Criteria for Continuation/Renewal

Continuing review must be substantive and meaningful. When considering whether or not to renew a study, the IRB revisits the same criteria used to grant initial approval. These include (but are not limited to):

- The risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
- The selection of subjects continues to be reasonable in relation to anticipated benefits;
- Informed consent continues to be appropriately obtained and documented;

- Significant new findings that have arisen during the study and which might relate to participants' willingness to continue participation have been provided to participants
- There are appropriate:
  - o Provisions for monitoring of the data to assure patient safety,
  - o Protections to ensure the privacy of subjects and confidentiality of data,
  - o Safeguards for vulnerable populations.

Because it may be only after research has begun that the real risks can be evaluated and the preliminary results used to assess the actual risk/benefit ratio, the IRB can then determine whether or not the study can be continued, or continued only with protocol modifications. In order to determine the status of the study, the following will be revisited at a meeting of the Full IRB when expedited review cannot be used:

1. The application for continuing review. This application contains:
   a. A brief summary of the research methodology and procedures
   b. The number of subjects entered and withdrawn (including the reason for withdrawal) for the review period and since the inception of the project
   c. The gender and minority status of those entered into the protocol
   d. The number of subjects considered as members of vulnerable populations
   e. A copy of the proposal (if different from the original submission) and all approved amendments
   f. A copy of the current consent document(s)
   g. A copy of the current HIPAA authorization document (if separate from the informed consent document)
   h. Information that may impact on the risk/benefit ratio such as ADVERSE EVENTS (AEs), unanticipated problems, and complaints regarding the research
   i. Research findings to date (if available)
   j. An assurance that all AEs have been reported as required
   k. New scientific findings in the literature, or other relevant findings, that may impact on the research

2. All IRB members shall receive a copy of the Continuing Review paperwork prepared and submitted by the Investigator.

3. Consent document: Each member of the IRB shall review the currently approved consent document and ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject in an updated consent document.

4. Continuing IRB review of research must occur even where the remaining research activities are limited to the analysis of data that include identifiable private information as defined in 45 CFR 46.102(f)(2). This remains the case even after a protocol has been closed at all sites and protocol-related treatment has been completed for all subjects.

IRB Review

The IRB will determine if it needs verification from sources other than the Investigator that no material changes have occurred since the previous IRB review. In this situation, the IRB may request an independent assessment of information or data provided in the renewal application. Studies with complicated protocols or atypical risks or those conducted by Investigators who have failed to respond to the IRB or IRB Chairperson in the past are examples of when verification may be needed. The IRB staff will alert the assigned reviewer by e-mail when there have been previous problems with an investigator. The scope and extent of such an independent assessment is determined on a case-by-case basis, and sources for such outside information could include copies of FDA or internal audits, literature searches and/or phone calls to the sponsor.

Possible Outcomes of Review for Continuation

As an outcome of continuing review, the IRB may authorize continuation of the research or require that the research be modified or halted altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol, such as frequency of monitoring, requirement for interim reports, or duration of approval period. Appropriate continuing review intervals are addressed with each review conducted by the IRB. The following factors are taken into consideration when determining the appropriate review interval, but are not limited to:

- Involvement of vulnerable populations;
- Involvement of recombinant DNA or other types of gene transfer protocols;
- Use of waiver of informed consent procedures;
- Classified research;
- Research for which participants would be exposed to additional risks, e.g., breach of confidentiality, phase I studies, disproportionate number or severity of adverse events; and
- Previous suspensions of the research due to non-compliance, record keeping or other concerns.

All actions of the IRB, including any changes required to obtain continued renewal approval, shall be provided in writing to the investigators by the IRB staff.

How the Continuing Review Date is Determined

When the IRB has determined that continuing review will occur no sooner than within one year, the date of continuing review is determined by using the date the protocol was reviewed and approved by the convened IRB or (for expedited review, the IRB chair). For protocols reviewed by expedited mechanisms, the continuing review must occur within one year of the date the protocol received approval.

Site Visits/Audits and Third Party Verifications

The IRB has the authority to observe, or have a third party observe, the consent process of research it has approved, and to verify that the study is being conducted as required by the IRB. The IRB may identify an IRB member to perform site visits or to use another party either affiliated with the institution or not, to verify information in the study application, or in any interim, continuing review or renewal submissions.

APPLICABLE REGULATIONS

45 CFR §46 Protection of Human Subjects

21 CFR §56 Institutional Review Boards

OHRP Guidance on Continuing Review 07/11/2002

Harrisburg University of Science and Technology
Institutional Review Board

Continuation of Approved Research Study

Please forward this form, filled out completely and signed either physically or electronically, to IRB@HarrisburgU.edu at least 4 weeks before the anniversary of the last IRB study approval date.

IRB File No. Click or tap here to enter text.
Original IRB approval date: Click or tap to enter a date.
Project Title: Click or tap here to enter text.
Principal Investigator: Click or tap here to enter text.

Please answer all of the following questions:

1. Have the risks and/or benefits to the subjects changed from those originally anticipated? ☐ Yes ☐ No

2. Did any adverse events or unanticipated problems involving risks to the subjects or others occur? ☐ Yes ☐ No

3. Have any subjects withdrawn, or have you excluded anyone from the study? ☐ Yes ☐ No

4. Have any subjects expressed discomfort or concerns or complained about the research? ☐ Yes ☐ No

5. Since the last IRB review, have there been any findings, publications, or other relevant information that relate to risks associated with the research? ☐ Yes ☐ No

6. Are any subjects participating in the study who have not signed a consent form? ☐ Yes ☐ No

If you answered "YES" to any of the above questions, please attach a detailed explanation, including actions taken to reduce the risks or discomforts to subjects and/or to communicate new findings or knowledge to subjects.

CERTIFICATIONS: I certify that the approved protocol and the approved method for obtaining informed consent, if applicable, have been followed during the period covered by this report and/or will continue to be followed throughout the continuation period.
I will continue to observe the ethical guidelines and regulations regarding the protection of human subjects from research risks and will continue to adhere to the policies and procedures of the Harrisburg University Institutional Review Board.
I agree to obtain informed consent of subjects who are to participate in this project according to the protocol approved by the IRB: to report to the IRB any unanticipated effects on subjects

which become apparent during the course or as a result of, experimentation and the actions taken as a result; to obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in an approved consent form; and to maintain documentation of consent forms and other research notes for at least three years after completion of the research.

Faculty members are responsible for maintaining for three (3) years files documenting student research for which they served as advisors.

This previously approved study has not been completed, and a continuation is requested.

Signature of Principal Investigator **Date**

Signature of Faculty Advisor **Date**

Submit this completed form to: IRB@HARRISBURGU.EDU

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

MODIFICATIONS (AMENDMENTS) TO PREVIOUSLY-APPROVED RESEARCH

I GENERAL PROCEDURE

A. Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects. Investigators or Sponsors must submit requests for changes to the IRB in writing. Upon receipt of the protocol change request, the IRB Chair or designee will determine if the revision meets the criteria for minor modification/change (i.e. involving minimal risk). If the change represents more than a minor modification or change it must be reviewed and approved by the IRB.

1. Determination of level of review

Minor modification/change - A proposed change in research-related activities that does not significantly affect an assessment of the risks and benefits of the study does not substantially change the specific aims or design of the study, does not involve the addition of procedures that involve more than minimal risk to subjects, and does not involve the addition of procedures that preclude the research from being reviewed using the expedited procedure.

Examples of **minor changes** to a research study include but are not limited to, the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of **significant changes** to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects (e.g., addition of a new drug to a treatment regimen; addition of invasive procedures; change in route or frequency of drug administration, etc.);

- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments

Amendments to protocols originally reviewed under expedited review criteria will originally be reviewed by the IRB chair. If an amendment for research previously approved under expedited review is determined to increase the level of risk beyond minimal risk, the amendment will be referred to the full-convened IRB for review. Significant modifications/changes must be reviewed by the convened IRB and cannot be reviewed by the expedited procedure for initial review, continuing review, or the review of modifications. All applicable regulatory criteria will be applied and reviewed when evaluating modifications to previously approved research.

Significant modifications/changes requiring full IRB Board review will be assigned to a primary reviewer who will be responsible for summarizing at the meeting the proposed modification(s) and its/their potential impact on research participants. In addition, all IRB members will receive copies of the request for modification and any pertinent documents submitted by the investigator(s) in support of the requested modification. Any modifications that were implemented without IRB approval to eliminate apparent immediate hazard to the participants will be reviewed by the full board to determine whether the change was consistent with ensuring the participants' continued welfare.

3. Actions

The IRB chair will review and approve amendments considered minor, and which do not require full Board review. The IRB chair may also identify restrictions that must be met prior to approval. If the IRB chair does not feel the amendment should be approved, it will be referred to the full Board for review. For other amendments, after review of the requested modification and supporting documentation, the IRB may take any action deemed appropriate for protection of subjects enrolled in the study. This includes approval of the modification, placing of restrictions that must be met prior to approval, deferment of approval until additional information is provided, or disapproval of the modification. These actions will be communicated to the investigator in written form.

B. Documentation

If an amendment has modified the consent document, the amended version will be stamped with the approval date of the new amendment, but will retain the expiration date of the original approval period.

Harrisburg University of Science and Technology
Institutional Review Board

Modification of Approved Research Study

Please forward this form, filled out completely and signed either physically or electronically, to IRB@HarrisburgU.edu with any changes.

Note: Do not use this form for changes made prior to IRB approval or in response to an IRB review.

IRB File No. Click or tap here to enter text.

Original IRB approval date: Click or tap to enter a date.

Project Title: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

Please check the type of modification being submitted:

☐ **Change in procedure addition deletion modification Describe:** Click or tap here to enter text.

☐ **Change in study personnel addition deletion modification Describe:** Click or tap here to enter text.

☐ **Change in research site addition deletion modification Describe:** Click or tap here to enter text.

☐ **Change in subject enrollment Increase or Decrease.**
Describe Click or tap here to enter text.

☐ **Recruitment Material/Advertisement Change**
Describe Click or tap here to enter text.

☐ **Consent/Assent/Permission form changes**
If this is checked, attach a copy of the current approved consent document and a copy of the proposed consent document with changes highlighted.
Describe: Click or tap here to enter text.

☐ **Other**

Describe Click or tap here to enter text.

Discuss if the modification(s) will affect research risk and/or benefits.

Click or tap here to enter text.

I understand that I cannot initiate any changes in my approved protocol before I have received IRB approval and/or complied with all contingencies/stipulations with regards to that approval.

_____ _____

Signature of Principal Investigator **Date**

_____ _____

Signature of Faculty Advisor **Date**

For IRB Use Only:

☐ **Minor, Non-substantive Change Approved by Expedited Review**

☐ **Substantive Change Requiring Convened IRB Review**

_____

Signature of Primary Reviewer **Date**

HARRISBURG UNICERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

ADVERSE EVENTS OR UNANTICIPATED PROBLEMS

I PURPOSE

The Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) recognize that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

II DEFINITIONS

Adverse events: Any unfavorable diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease shown by the participant which either occurs during the study, having been absent at baseline, or, if present at baseline, appears to worsen. The event may have been anticipated by the protocol and listed as a side effect in the consent form. It is an adverse event even if the event is not associated with the study or caused by the investigational agent. In addition, occasions may occur where an adverse event has not yet occurred, but is likely to occur, as determined by an IRB, research, or clinical team member, unless preventative measures are taken. This is defined as an imminent threat of an adverse event in research and must also be reported as if an actual adverse event had occurred.

Serious adverse events **-** Any untoward medical occurrences that: (1) result in death, (2) are life threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) cause serious, persistent or significant disability or incapacity, (5) result in a congenital anomaly or birth defect, or (6) causes cancer, or (7) results in an overdose of the investigational drug or (8) is any medical event that requires treatment to prevent one of the medical outcomes listed above.

Non-Serious Adverse Event: An adverse event which appears not to have harmed or have the potential to harm participants. The Adverse Event may or may not have been contemplated and listed as side effect in the Informed Consent document.

Expected Adverse Events - Adverse events described in the Package Insert on FDA approved drugs, biologics or devices; adverse events described in the FDA Investigator's Brochure/Device Description for investigational drugs, biologics or devices.

Unexpected Adverse Events - An event is unexpected when the event or its severity are not accurately reflected in the informed consent document, current investigator brochure or product

labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

Relationship of Adverse Event to Study Drug or Procedure
Adverse events may be related (are or may have been caused by the study drug or procedure) or unrelated (clearly due to extraneous causes (e.g., underlying disease, environment) to the study drug or procedure.

The following criteria may be used to determine the likelihood that an adverse event is related to the study drug or procedure:

Unlikely (must have 2):

1) does not have temporal relationship to intervention,
2) could readily have been produced by the subject's clinical state,
3) could have been due to environmental or other interventions,
4) does not follow known pattern of response to intervention,
5) does not reappear or worsen with reintroduction of intervention

Possibly Related (must have 2):

1) has a reasonable temporal relationship to intervention,
2) could not readily have been produced by the subject's clinical state,
3) could not readily have been due to environmental or other interventions,
4) follows a known pattern of response to intervention

Probably Related (must have 3):

(1) has a reasonable temporal relationship to intervention,
(2) could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions,
(3) follows a known pattern of response to intervention,
(4) disappears or decreases with reduction in dose or cessation of intervention

Definitely Related (must have all 4):

(1) has a reasonable temporal relationship to intervention;
(2) could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions;
(3) follows a known pattern of response to intervention;
(4) disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.

Unanticipated Problem – Any problems that were not contemplated when the research was approved (i.e. are unexpected) and which present risk of serious harm to subjects or to others, including the research team, the university community, or the broader community. Unanticipated problems are always related to an approved study, either ongoing or closed. Adverse events may meet the criteria for unanticipated problems when they are unexpected, related or possibly related to participation in research, and serious in nature.

Examples of Unanticipated Problems (other than adverse events) that present the risk of serious harm to participants and must be reported to the IRB are:

- subpoena to the PI for sensitive participant data;
- the arrest of a PI on a felony charge;
- the pregnancy of a participant in a study of an unapproved drug;
- the incarceration of a participant
- the loss of copies of participant data carelessly left somewhere outside the study site (or other breaches of confidentiality);
- the results of data safety monitoring of the investigational agent showing an unexpected toxicity that puts other participants at risk.
- complaints
- protocol deviations (e.g. unapproved modification to a research protocol)
- sponsor-imposed suspension for risk.

Protocol deviation – Any unapproved deviation from the protocol, including deviations from eligibility criteria or patient visits outside the time specified in the protocol.

Significant protocol deviation - Any unapproved deviation from the protocol that significantly affects the safety of the subject, the scientific quality of the study, or the safety of researchers. Protocol deviations can include deviations from eligibility criteria, from the manner of completing pretreatment procedures, in using an incorrect from form obtaining informed consent or failing to reconsent a participant when required by the IRB, in administering study treatments, complications from study procedures, or failures of safety monitoring.

Complaints - an expression of dissatisfaction or concern about safety, privacy or protection of a subject regarding human subject research.

- Minor complaint – a complaint that alleges an inconvenience to human participants but does not result in an unanticipated problem or serious adverse event or increase in risk. Examples are questions about the amount of participant payment; no close parking available; study personnel were rude; incorrect form was used.
- Major complaint – a complaint that alleges that human participants are being put at risk or increased risk compared with what is described in the consent form. Examples are PI not allowing enough time for the consent process; PI not following inclusion/exclusion criteria; failure to follow protocol; failure to report unanticipated problems or SAEs; participant feels like their rights have been violated; PI not complying with HRC policies or federal regulations; a series of minor complaints.

III REPORTING REQUIREMENTS

A. For Adverse Events Involving Participants From HU Sites

All events that are unexpected, related or possibly related to the study, or suggest that participants are at greater risk than was previously known or recognized, must be reported. All reported adverse events related to the study will be reviewed to determine if they are unexpected and serious, and if they warrant a re-evaluation of the risk level of the study. If subject complaints arise from an observational study, the IRB should be notified in writing of the subject's concern and how the concern was addressed.

For adverse events that are unexpected, related or possibly related to the study, the principal investigator must submit a report to the IRB within the required time frame for reporting as described in the chart below. Investigators are encouraged to report events as soon as possible within the required time frame shown in the table below.

SEVERITY OF THE EVENT	NATURE OF THE EVENT	RELATIONSHIP OF THE EVENT	REPORTING TO THE IRB
Serious[1]	Expected[2] Unexpected	Definite Probably Possible Unlikely Unrelated	Report immediately (within 24 hours) to the IRB Chair or Provost by telephone or email followed by a written report to the IRB Chair within 10 working days.
Moderate Minor	Unexpected	Definite Probably Possible	Report in writing to the IRB Chair within 20 working days
Moderate Minor	Unexpected	Unlikely Unrelated	Summarize events in progress report at continuing review
Moderate Minor	Expected	Definite Probably Possible Unlikely	Summarize events in progress report at continuing review
Non-serious	Expected Unexpected	Definite Probably Possible Unlikely Unrelated	Summarize events in progress report at continuing review

1 Report all serious adverse events that occur after active study participation for a minimum of 30 days post-study discontinuation or as specified in the protocol, whichever time period is greater

2 Reporting of expected serious adverse events to the IRB is not required prior to continuing review for NIH-sponsored cooperative Group trials, such as NCSI-sponsored oncology trials or certain AIDS trials. Refer to the sponsor's protocol for specific reporting requirements

B. For Adverse Events From Sponsor Regarding Adverse Events At Sites External To HU

When adverse events are reported in a study that is not being conducted at HU or one of its affiliated institutions, the investigator should review the event and answer the following questions:

1. Is the adverse event Serious and Unexpected?
2. Is the adverse event related to the study drug/device/procedures (based upon the assessment of the HU investigator)?

If the answer to **both** of the above questions is "Yes" then the event should be reported to the IRB. In addition, if a change to the protocol or consent form is necessary, the standard process for submitting these modifications to the IRB should be followed. If the answer to **either** of the questions is "No" then the Adverse Event does not need to be submitted to the IRB but should be **filed** with the investigators research documents as required by the protocol.

C. For Unanticipated Problems (Other Than Adverse Events)

1. If reporting is required, the investigator should complete and submit the Adverse Event/Unanticipated Problems Report.

2. When an Unanticipated Problem occurs, the principal investigator (PI) must do the following:
   a. Report in writing within ten (10) working days of the date the researcher becomes aware of the problem. If the unanticipated problem poses an immediate threat to the participant or others, report to the IRB within (1) business day by telephone or e-mail with a follow-up in writing.
   b. Complete and submit the Adverse Events/Unanticipated Problems Report Form and submit any corroborating reports to the IRB.
   c. Inform, in writing the appropriate research team members, pharmacist, support staff, administrative officials, and funding or sponsoring agencies if applicable of the unanticipated problem.

3. Specific guidance for situations involving noncompliance is provided in IRB policy (Non-compliance with the Requirements of the Human Research Protection Program).

IV IRB REVIEW PROCESS

A. ADVERSE EVENTS

1. Principal Investigators will submit required reports of adverse events as defined in the previous sections. The IRB Chair will review all adverse event reports submitted to determine whether they are serious adverse events involving risks to participants or others that may require action prior to the next IRB meeting. The IRB Chair may choose to refer the report to another IRB member or to the full committee for review. All reported adverse events that occur locally will be reviewed by the IRB board at its next meeting.

2. The IRB will individually review all reported local adverse events and determine if there are unanticipated problems involving risks to participants and others. This finding will be entered into the minutes of the meeting.

3. If the event is determined to be an unanticipated problem involving risk to participants or others, it will be handled as described in (B) below.

4. Questions to be considered when reviewing an adverse event:

a. Date and time of onset of adverse event.
b. Was the event/problem from this institution, or another participating site if a multi-center sponsor or study?
c. Was the event/problem deemed mild, moderate, severe, or fatal? If fatal, date of death, including copy of the death certificate and autopsy report should be obtained.
d. Was the event/problem expected or unexpected?
e. Was the event/problem related to the research intervention (study related)?
f. What was the outcome? Is it resolved, ongoing or did the subject die?
g. Based on this event, will additional monitoring of other patients be performed in the study to detect similar problems early?
h. Are the possibility, severity and specificity of this event described in the consent form, protocol, and investigator brochure for this study?
i. Will the consent procedures be revised as a result of this event? Has the revised consent been submitted to the IRB?
j. Will patients already enrolled in the study be informed about the possibility of this adverse event? If yes, how?

5. The reviewer(s) shall report on the following to the IRB at a convened meeting:
a. Additional risks that may need to be included in the risk section of the consent form.
b. An increase in risks that may indicate the need to halt study enrollment; close the study entirely; or modify the study design.
c. If the reviewers (or the Committee) feel it necessary to supplement their review, they may request an outside "expert" to review and comment
d. Approval of the description and reporting of the adverse event.

6. The IRB may suspend or terminate research if the information gained during its review of the adverse events indicates that human subjects in a research project are exposed to unexpected serious harm. [21CFR 56 108(b)(1); 45 CFR 46 103(b)(5)] When such action occurs, the IRB will provide a written statement of action to the investigator, and the Provost or designee will notify the sponsor and governing regulatory authority in writing of all protocols suspended for cause. This notification will include the reason for suspension and the action taken to resolve the issue. All notification will occur within 10 days.

7. The IRB may accept the findings of the PI and designated reviewers. The AE report will be placed in the protocol file and reported during continuing review.

B. Unanticipated Problems

The IRB Chair will initially review reports to determine whether the reported event is an unanticipated problem involving noncompliance (see Policy), involving risks to participants or others, is serious, or is continuing in nature. If uncertain, the coordinator will immediately refer the report to the IRB Chair or designee. The Chair or designee will review and assess the facts of all reported events, including review of the related IRB records and the IRB approved protocol.

The IRB Chair may consult with others to achieve a more thorough or faster assessment.

If the IRB Chair decides that the reported incident is an unanticipated problem involving noncompliance, involving risks to participants or others, is serious, or is continuing in nature, he/she will bring the problem to the attention of the IRB at its next convened meeting. The IRB members will be provided with a copy of the report, documents from the IRB records concerning the report, and have available the approved protocol for necessary and appropriate deliberations. The IRB may interview the researcher who reported the problem or the principal investigator of the research study.

1. If the IRB determines that the event was **not** an unanticipated problem involving noncompliance, does not involve risks to participants or others, is not serious, and is not continuing in nature, no further action will be taken.

2. If the convened IRB determines that the event was an unanticipated problem involving risks to participants or others, the IRB will take action as described in Policy (Non-compliance with the Requirements of the Human Research Protection Program)

C. IRB Reporting Of Adverse Events Or Unanticipated Problems

Any adverse event or unanticipated problem reviewed by the IRB will be recorded in the minutes of the meeting at which it was reviewed. The minutes will reflect whether the problem involved noncompliance, risks to participants, is serious in nature, and/or is ongoing in nature.

Any substantive action taken by the IRB (defined as an action that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the AE in research) must be reported in writing to the HU Provost, the investigator's program lead, and the HU President.

Within 10 days the Provost will inform OHRP, for federally funded studies, the FDA for studies involving drugs, devices, and biologics, the sponsor of the study and any other applicable regulatory agency of the action taken.

Harrisburg University of Science and Technology
Institutional Review Board
UNANTICIPATED PROBLEM REPORT FORM

Please forward this completed form, signed either physically or electronically, to IRB@HarrisburgU.edu if an unanticipated problem occurs during the study.

IRB File No. Click or tap here to enter text.
Project Title: Click or tap here to enter text.
Date of this report: Click or tap to enter a date.
Project Title: Click or tap here to enter text.

Primary Investigator: Click or tap here to enter text.
Email: Click or tap here to enter text.

Faculty Advisor (if applicable): Click or tap here to enter text.
Email: Click or tap here to enter text.

PART I- BASIC INFORMATION

1. Date the unanticipated problem occurred: Click or tap to enter a date.

2. Date the research team became aware of the problem: Click or tap to enter a date.

3. Where did the problem occur? Click or tap here to enter text.
   Was this site inside ☐ or outside ☐ the university campus?

4. Does the study include a drug? ☐ Yes ☐ No
   If yes, provide the name of the drug(s): Click or tap here to enter text.
   Date of last study drug administration: Click or tap to enter a date.

5. Does the study include a medical intervention or device? ☐ Yes ☐ No
   If yes, provide the name of the intervention or medical device(s):
   Click or tap here to enter text.

6. Date of latest study-related intervention or interaction (relevant to this event):
   Click or tap to enter a date.

7. Description of latest study-related intervention or interaction (relevant to this event): Click or tap here to enter text.

8. Was there harm, complaint, or death of the participant? ☐ Yes ☐ No
   If yes, describe the harm, complaint, or event of death of the participant.

Click or tap here to enter text.

PART II: DESCRIPTION OF UNANTICIPATED PROBLEM
(Adverse Event, Incident, Experience or Outcome)

1. List key words describing the problem (e.g., breach of confidentiality):
   Click or tap here to enter text.

2. Briefly describe the problem: (identify/describe the medical nature of the unanticipated problem, including background, relevant history, major medical or physical problem, types of medication or treatments and dates.)
   Click or tap here to enter text.

3. If it is a social/behavioral study, include information such as nature of the unanticipated problem, description of the situation that led to the problem, individuals present, referral for medical/psychological care, etc.)
   Click or tap here to enter text.

PART III. CHARACTER OF UNANTICIPATED PROBLEM

☐ Yes ☐ No The problem is **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
If yes, explain the basis for determining that the problem is unexpected: Click or tap here to enter text.

☐ Yes ☐ No The problem is **related or possibly related** to participation in the research *(possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). **If yes, explain the basis for determining that the problem is related or possibly related:** Click or tap here to enter text.

☐ Yes ☐ No The problem **places participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously recognized. **If yes, explain the basis for determining that the problem placed participant or others at a greater risk of harm:** Click or tap here to enter text.

IV. CORRECTIVE ACTIONS

☐ Yes ☐ No **Should the protocol be revised?**
If yes, provide a description of the proposed protocol changes: (Attach a protocol modification form with a revised protocol for any proposed change to the protocol.) Click or tap here to enter text.

☐ Yes ☐ No **Should the research be suspended?**
If yes, describe the procedures you will follow for the suspension or termination of the research. Click or tap here to enter text.

☐ Yes ☐ No **Should enrolled participants be notified about the problem/event?**
If yes, attach a protocol modification form with a revised consent form or draft letter of notification with this report.

☐ Yes ☐ No **Should other corrective action be taken in response to the unanticipated problem?**
If yes, provide a description of the proposed corrective action:
Click or tap here to enter text.

_____ _____
Signature of Investigator Date

_____ _____
Signature of Faculty Advisor or Dissertation Chair Date

For IRB Use Only

IRB Chair/Designee Review of Problem Report:

☐ The Institution was notified via confidential reporting by participant or observer.

The Problem:

☐ Does **not** represent an unanticipated problem involving risks to participants or others (review by expedited procedures)

☐ Does represent an unanticipated problem involving risks to participants or others (refer to convened IRB for review)

_____ _____

Signature of IRB Chair/Designee Date

Office of Human Research Protection

OHRP Recommendations for unanticipated problems involving risks to subjects or others:

A detailed description of the problem; and Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

For serious or continuing noncompliance:

Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

For suspension or termination:

A detailed description of the reason for the suspension or termination; and actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

Time frame for reporting incidents:

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report and indicate that a follow-up or final report will follow by the earlier of a specific date; or when an investigation has been completed or a corrective action plan has been implemented.

OHRP focus on corrective actions when reviewing incident reports:

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of non-compliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of the corrective actions taken by the institution. OHRP assesses whether the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution wide.

OHRP response to incident reports:

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will either state that the report was adequate or request additional information. For questions on reporting, please contact the Director of the Division of Compliance Oversight, 240-453-6900 or 866- 447-4777.

Where to send incident reports:

Send reports (PDF or Word documents preferred) to the following email address: IRPT.OS@hhs.gov **if applicable**

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

ADMINISTRATIVE HOLD, SUSPENSIONS AND TERMINATIONS OF IRB-APPROVED RESEARCH

I DESCRIPTION

The IRB has the authority to place on hold, suspend or terminate approval of research that is not being conducted in accordance with federal, state or local regulations or institutional or IRB requirements, or that has been associated with unexpected serious harm to participants. The IRB shall promptly notify the PI, Provost and regulatory authorities, as appropriate, of the IRB's actions and reasons for the actions.

II RESPONSIBILITY

The IRB chair and full IRB will determine when to place on hold, suspend or terminate a research project. All such actions will be reported at the convened IRB meeting in the Information section of the agenda.

III PROCESS

PI-Imposed Suspension

The PI may place specific research activities on hold temporarily to further review data or the conduct of the study to ensure that the rights and welfare of participants remain favorable. The PI will notify the IRB in writing of his/her decision to suspend some or all of the research activities and the reason for doing so. The PI will also notify the IRB whether participants are to be informed of the suspension, and the justification for either informing or not informing the participants. Once the PI lifts the suspension, the PI will notify the IRB in writing. The IRB may request additional information regarding the PI-imposed suspension so that the IRB may monitor the protocol. Adverse events and outcomes must continue to be reported to the IRB.

Sponsor-Imposed Suspension

The sponsor of a research study may place specific research activities on hold temporarily to further review data or the conduct of the study to ensure that the rights and welfare of participants are protected. The sponsor will notify in writing, either the IRB directly or the PI, of the decision to suspend some or all of the research activities and the reason for doing so. The sponsor will also notify the IRB whether participants are to be informed of the suspension, and the justification for either informing or not informing the participants. Once the sponsor lifts the suspension, the PI or sponsor will notify the IRB in writing. The IRB may request additional information regarding the sponsor-imposed suspension so that the IRB may monitor the protocol. Adverse events and outcomes must continue to be reported to the IRB.

IRB-Imposed Suspension

A suspension for cause is when the IRB temporarily stops some or all research activities, or permanently stops some research activities, or both. Following a suspension for cause, continuing review is still required. The IRB chair or convened IRB may order a suspension for cause. If the IRB chair orders the suspension for cause, the chair will report this to the IRB at the next convened meeting. The IRB will review the circumstance and vote to uphold or overturn the suspension. Before instituting a suspension for cause, the person or IRB ordering the suspension will consider whether stopping procedures might harm current participants. If so, the person ordering the suspension will consider procedures to protect their rights and welfare, such as allowing them to continue in the research, transferring the research protocol to another investigator, or arranging for alternative medical care. The IRB will notify the PI in writing that the protocol has been suspended and for what cause. The IRB will ensure that current participants are notified of the suspension whenever participants are undergoing interventions or interactions. The IRB will decide whether follow-up of participants for safety reasons is required. If so, the Investigator will inform current participants of this fact. When the IRB requires follow-up of participants for safety reasons, the investigator must report any adverse events or outcomes to the IRB. If the concerns are not addressed, the IRB may terminate the research or take other action it deems appropriate to protect the health and welfare of participants. If the suspension for cause involves a temporary halt to research procedures and the issues leading to the suspension are resolved, the IRB may lift that portion of the suspension.

The IRB may suspend temporarily some or all research procedures pending an investigation by the IRB and/or other reviewing committee on allegations of noncompliance of noncompliance or the appearance of immediate harm to the health or welfare of participants. The IRB will notify the PI in writing that the protocol has been suspended and for what cause. The PI will then be requested to comment and provide information on the issue causing the suspension. The IRB will request that the PI explain how the situation occurred and how he or she will ensure that this situation will not occur in the future. The IRB may require changes to the protocol, consent form or any other protocol documents as it determines to adequately remedy the situation and protect the health and welfare of participants. The PI may be required to receive new or additional training in a certain area to demonstrate their competence to perform the research. Additional oversight of the conduct of the protocol or a transfer of responsibility to another investigator may also be recommended. When the PI has adequately addressed the concerns, the IRB may lift the suspension on the research. If the concerns are not addressed, the IRB may terminate the research or take other action it deems appropriate to protect the health and welfare of participants.

The person or IRB ordering the suspension for cause will immediately notify the Provost within 24 hours. The Provost will notify the sponsor and applicable regulatory authority(s) (see below) in writing of all protocols suspended for cause within 10 days.

> The Provost will inform the FDA for studies involving drugs, devices, and biologics, and as appropriate the sponsor of the study and any other required regulatory agency of the action taken.

PI-Imposed Termination

To allow for substantive and meaningful review of research activities at the close of a study, the investigator is required to submit a Final Study Close-Out Report Form (available on the web, and at the end of this procedure). This form is required for studies approved by the full board or by expedited review. It is not required for exempt studies. The report updates the IRB on the conduct and outcomes of the study, including any risks or problems that may have arisen since the last study renewal and which may need to be disclosed to the study participants or others.

If a researcher is terminating employment or association with Harrisburg, the investigator should either:

1. Close the study and submit a final Study Close-Out form to the HU IRB
   or
2. Transfer the protocol to another HU investigator (via submission of an amendment/modification request) as the new Principal Investigator.

IRB-Imposed Termination

A *termination for cause* is when the IRB permanently stops all research activities. Following a termination for cause, continuing review is no longer required. The IRB chair or convened IRB may order a termination for cause. If the IRB chair orders the termination for cause, the chair will report this to the IRB at the next convened meeting. The IRB will review the circumstance and vote to uphold or overturn the termination. Before instituting a termination for cause, the person or IRB ordering the termination will consider whether stopping procedures might harm current participants. If so, the person ordering the suspension will consider procedures to protect participants rights and welfare, such as allowing them to continue in the research, transferring the research protocol to another investigator, or making arrangements for alternative medical care. The IRB will notify the PI in writing that the protocol has been terminated and for what cause. The IRB will ensure that current participants are notified of the termination whenever participants are undergoing interventions or interactions. The IRB will decide whether follow-up of participants for safety reasons is required. If so, the PI will inform current participants of this fact. When the IRB requires follow-up of participants for safety reasons, the investigator must report any adverse events or outcomes to the IRB.

The IRB may stop permanently some or all research procedures for cause if it finds after an investigation that the significant noncompliance to the protocol or regulations presents a possibility of harm to the health and welfare of participants. The IRB will notify the PI in writing that the protocol has been terminated and for what cause. The PI will then be requested to comment and provide information on how the situation occurred and how he or she will ensure that this situation will not occur in future projects. The PI and research staff may be required to receive new or additional training in a certain area to perform future research. If the PI requests to pursue the research, he/she must address all concerns of the IRB and then resubmit the protocol for consideration of approval.

The person or IRB ordering the termination will immediately notify the Provost within 24 hours. The Provost will notify the sponsor and applicable governing regulatory authority(s) as described in the previous section (on suspensions) in writing within 10 days of all protocols terminated for cause.

Administrative Closure

A protocol submission under review by the IRB, in which final approval has not yet been granted or released, will be administratively closed six months from the date of submission receipt or pending approval. At the six-month date, the PI will be notified by the IRB director or designee regarding the expiration. If the PI provides adequate justification to keep the protocol in the review process, the protocol will be given another six-month period for the PI to obtain IRB approval. Those protocols for which adequate justification has not been received at the six-month date or those protocols that remain in review status at the one-year date will be administratively closed by the IRB.

HARRISBURG UNIVERSITY
INSTITUTIONAL REVIEW BOARD

STUDY COMPLETION REPORT FORM

IRB File No.: Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.
Email Address: Click or tap here to enter text.

Faculty Advisor: Click or tap here to enter text.
Email Address: Click or tap here to enter text.

Original Approval Date: Click or tap to enter a date.

This project has been completed.

FINAL REPORT:

1. Was there any deviation from the originally anticipated risks and/or benefits of the study? ☐ Yes ☐ No

2. Did any adverse events or unanticipated problems involving risks to the subjects or others occur? ☐ Yes ☐ No

3. Did any subjects withdraw or did you exclude anyone from the study? ☐ Yes ☐ No

4. Did any subjects express discomfort or other concerns or complain about the research? ☐ Yes ☐ No

5. Did any subjects participate in the study without signing a

consent form? ☐ Yes ☐ No

6. To the best of your knowledge, are there any long-term risks to the subjects that were not previously identified or anticipated? ☐ Yes ☐ No

If you answered "YES" to any of the above questions, please attach a detailed explanation, including actions taken to reduce the risks or discomforts to subjects and/or to communicate new findings or knowledge to subjects.

*(**NOTE:** Per Federal guidelines, future analysis of data from this study to address additional research questions will require a new IRB application.)*

CERTIFICATIONS: I certify that the approved protocol and the approved method for obtaining informed consent, if applicable, have been followed during the period covered by this report. I agree, for IRB purposes, to maintain documentation of consent forms and other research notes for at least three years after completion of the research.

Faculty members are responsible for maintaining files of student research for which they served as advisors.

_____

Signature of Principal Investigator **Date**

_____ _____

Signature of Faculty Advisor **Date**

Submit to: IRB@HarrisburgU.edu

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

OBTAINING INFORMED CONSENT IN HUMAN SUBJECTS RESEARCH POLICY

No investigator may involve a human being as a participant in research unless the investigator has first secured the participant's informed consent or the IRB has waived the requirement that informed consent be obtained. If the participant is not competent to give informed consent, the investigator may get informed consent from a legally authorized representative. The "legally authorized representative" is determined by the law of the state where the research is being conducted. In many jurisdictions, the representative who can give informed consent for medical procedures is not the same as the representative who can give consent for research procedures.

I THE INFORMED CONSENT PROCESS

- The Informed Consent Process will be described in the protocol or petition and reviewed by the IRB.
    - The IRB approval of the wording contained within the consent document will be shown through the use of a stamp placed on each page of the informed consent that indicates the date of the most recent IRB approval of that document.
- The investigator or other study personnel who conduct the consent process must present information objectively so as to minimize the possibility of coercing the individual to participate or using undue influence.
- Prospective participants must be given sufficient time to consider whether to participate in the study and must have the opportunity to have all their questions answered.
- The researcher must provide information in language that is understandable to the participant.
- When the IRB believes appropriate, the investigator may be required to use tools or techniques that assess and confirm a participant's understanding of the consent. Such techniques may include using a written comprehension tool, requiring a friend or family member to be present, requiring a waiting period or prior approval of the research by a community review board.
- The informed consent process will not contain any language through which the participant waives or appears to waive any legal rights or releases the investigator, the institution, the sponsor or its agents from liability for negligence.
- The IRB, the Provost, or the designee of any of these has authority to observe the consent process for any approved study. This may be done as one means to protect participants, particularly if there is cause for concern (for example, if there have been complaints registered by participants).

II DOCUMENTATION OF INFORMED CONSENT

Unless the IRB has waived the requirement for written informed consent, the investigator must get documentation of informed consent by use of a written consent form, approved by the IRB that is signed and dated by the participant or the participant's legally authorized representative. This consent must embody the basic and appropriate elements of disclosure (see following section). All informed consent forms should be written at a level appropriate for the potential population. General formatting, readability and clarity must be acceptable to the IRB, and medical terminology must be defined in lay terms, ideally at a 7th grade (or lower) reading level. The participant (or the participant's legally-authorized representative) must be given adequate opportunity to read the consent document before it is signed.

In addition to the signature of the subject providing consent, the person obtaining consent of the subject must also execute the consent form. These individuals must: 1) complete required human subjects protection training; 2) complete a Significant Financial Interest Disclosure; 3) be listed on the IRB petition and approved by the IRB as "investigator" or "key personnel"; 4) be trained on the protocol as documented in writing; and 5) delegated by the principal investigator to obtain informed consent. Note that for studies involving medical treatment, the physician investigator ordering and overseeing the treatment will determine subject eligibility but may sign the informed consent form proximate to the date of the subject's enrollment when not immediately available. For multi-center studies, the sponsor may identify who will obtain informed consent and how this will be documented. Please consult with the IRB Chair, the sponsor, the performing location (e.g. hospital), etc. for guidelines to follow.

a. The IRB discourages the use of a signature/initial field on each page as this does not add to the consent process, and is easily missed resulting in noncompliance.
b. The IRB does not require (but does not forbid) that the time of consent be documented in the signature fields.

The researcher will give a copy of the signed informed consent to the participant, and the original will be placed in the research record maintained by the investigator. The IRB, the Provost, the sponsor of the research, regulatory and accrediting agencies, and the designees of any of them are authorized to randomly review protocols for compliance with informed consent requirements.

The IRB may approve a telephonic consent procedure under which the subject's legally authorized representative ("LAR") is sent a scanned or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return email (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process. Both the LAR and the incompetent adult patient must agree to participate. The LAR may not force the

incompetent patient to participate against his or her will. The following may serve as legally authorized representatives:

a. A health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document
b. A court-appointed guardian of the person

III REQUIRED ELEMENTS OF INFORMED CONSENT FORMS

In accordance with 21 CFR 50.25, and 45 CFR 46.116, the following information will be provided to each participant:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

    a. **Differentiating Usual Care from Research.** If this is an interventional study, the investigator provides for usual care. The subject needs to be able to identify which activity (e.g., treatment or service) is research, and which is usual care, and know who (the researcher or the subject's health care provider) is responsible for:
        i. Explaining potential risks and benefits of the treatment or service to the subject;
        ii. Providing the treatment or service;
        iii. Monitoring the treatment or service, as applicable;
        iv. Defining whether the adverse events result from usual care or research, as applicable;
        v. Alerting the subject if there is a problem with the treatment or service (e.g., a newly discovered risk, a product recall); and
        vi. Documenting the subject's clinical course while receiving the treatment or service, as applicable.
    b. This information will optimally be included in the consent document (or it must be documented how this information will otherwise be provided to the subjects)

2. A description of any reasonably foreseeable risks or discomforts to the participant.

    Note: Usual Care. *The investigator, or designee, must ensure the Informed Consent process clearly defines for the subject which potential risks are related to the research (see subpar. 10g and 38 CFR 16.116(a)(2)) and, therefore, must be discussed with the research team versus those associated solely with usual care provided by the subject's health care provider.*

3. A description of any benefits to the participant or to others that may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant.

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. In the case of FDA-related research, the consent process must disclose a statement noting the possibility that the FDA may inspect the records. The consent form will include all individuals and organization that have access to a participant's record, including the sponsor, funding entities, agents of Harrisburg University, and any other federal agencies.

6. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

7. Protocols that are carried out at affiliated institutions (or institutions not a part of Harrisburg University) will carry only the compensation statement required by that institution's specific policy.

8. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.

9. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

IV ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, one or more of the following elements of information will also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) that are currently unforeseeable;
2. Circumstances under which participation may be terminated by the investigator;
3. Additional costs to the participant that may result from participation in the research;
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant;
6. A statement about the amount and schedule of all payments.
7. The approximate number of participants involved in the study;
8. Additional information that, in the judgment of the IRB, would add meaningfully to the protection of the rights, safety, and well-being of the participants.

V THE RESEARCHER'S OBLIGATION TO PROVIDE ADDITIONAL INFORMATION

Researchers have an obligation to continue to provide information to participants or their legally authorized representatives throughout the study so that they can continue to consent to participation. If new information becomes available during the course of the study that could influence a participant's decision, the researcher must inform the IRB, and if required by the IRB, must re-consent participants describing the new information.

VI WAIVER OR ALTERATION OF SOME OR ALL ELEMENTS OF INFORMED CONSENT

1. The IRB may approve a consent form which does not include, or which alters, some or all of the elements of the informed consent. In some cases this will occur because the study involves deception (the intentional misleading of subjects or the withholding of full information about the nature of the experiment). Federal regulations permit but establish limitations on the use of deception. The investigator must provide scientific and ethical justification for deceptive procedures for the IRB review and approval. The missing information should not increase the risks of the study, and subjects must be fully debriefed. Subjects must have the opportunity to ask questions about the new information and be given the opportunity to withdraw from the study and have their data removed. Deception may not be utilized to obtain enrollments.

   The investigator must show, and the IRB must document in its approval, that all of the following criteria have been met:

   a. The research involves no more than minimal risk to the participants;
   b. The waiver or alteration will not adversely affect the rights and welfare of the participants;
   c. The research could not practicably be carried out without the waiver or alteration;
   d. The research is not subject to FDA regulation.

2. When deemed appropriate, the IRB may require the investigator to prepare a written description of the research to be given to the participants (either before or after participation as appropriate to the study). The IRB will review this description as part of the approval process. If subjects have been deceived during participation in research activities, the HU IRB expects investigators to debrief subjects after their participation. The debriefing should include a detailed description of the ways in which deception was used. The investigator is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols.

3. Consent may also be altered or waived for certain research or demonstration projects conducted by or subject to the approval of state or local government officials that are designed to study public benefit or service programs when the research is not subject to FDA regulation. See 45 CFR46 116 (C)

VII WAIVER OF INFORMED CONSENT DOCUMENTATION

Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol. For research that presents greater than minimal risk of harm, a written copy of what the subjects will be told must also be submitted for review by the IRB at the time of the exemption decision.

VIII WAIVER OF ALTERATION OF THE PRIVACY RULE'S AUTHORIZATION (HIPAA) REQUIREMENT

The Privacy Rule (45 CFR parts 160 and 164) establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization by the IRB.

A waiver can occur when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria set forth in the Privacy Rule have been met. For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be impracticable to conduct the research if Authorization were required, an IRB could waive all or the authorization requirements for research participants if the IRB determined that all of the Privacy Rule waiver criteria had been satisfied. If the IRB approves such a waiver, the receipt of the requisite documentation of the approval permits a covered entity to use or disclose PHI in connection with a particular research project without Authorization. A partial waiver of the Authorization requirements of the Privacy Rule might be requested, for instance, to allow a researcher to obtain PHI as necessary to recruit potential research subjects. For example, even if an IRB does not waive the Authorization requirement for the entire research study, an IRB may partially waive the Authorization requirement to permit a covered entity to disclose PHI to a researcher for the purposes of contacting and recruiting individuals into the study.

An IRB may also approve a request that removes some, but not all, required elements of an Authorization. For example, an IRB may alter the Authorization to remove the element that describes each purpose of the requested use or disclosure where, for example, the identification of the specific research study would affect the results of the study.

Requests for alteration on minimal risk studies (i.e. those originally approved by expedited review) may be approved by the IRB chair. Other requests may only be granted by the full IRB board. For a covered entity to use or disclose PHI under a waiver or an alteration of the Authorization requirement, the IRB must determine (and document in the minutes and to the investigator) that the following criteria have been met:

a. The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of:
    - (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
    - (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and
    - (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule
b. The research could not practicably be conducted without the requested waiver or alteration
c. The research could not practicably be conducted without access to the PHI.

The IRB must specifically describe the PHI for which use or access has been determined to be necessary in connection with the specific research activity.

IX OBTAINING CONSENT FROM THOSE WHO CANNOT SPEAK ENGLISH

Individuals unable to speak English may not be excluded from participating in a study, unless the approved research protocol requires that subjects speak English. Investigators must provide an ethical and scientific justification for excluding non-English speaking subjects from research. Inconvenience or expense for the investigators is not an acceptable justification for excluding non-English speaking subjects.

The federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that informed consent information be presented to a research subject "...in language that is understandable to the subject (or authorized representative)" and, except in infrequent situations, be documented in writing. Subjects who are not English - speaking should be provided with a translation of the consent document in a language understandable to them. The federal regulations (45 CFR 46.117 and 21 CFR 50.27) permit two methods by which this requirement can be fulfilled: (1) a written consent document translated into a language understandable to the subject (or their legally authorized representative), e.g., foreign language translation of the IRB approved English informed consent form or (2) a "short form" written consent document stating that the elements of consent have been presented orally to the subject (or legally authorized representative). The IRB determines which procedure is appropriate for documenting informed consent on a protocol specific basis. In general, the short form process (see below) is appropriate only for those occasions where a non-English speaking subject needs to be enrolled in a study that had not planned on enrolling persons speaking another language. Providing a written translation of the full English consent document is required when:

- The research targets a specific population that is non-English speaking
- A significant proportion of subjects are anticipated to be non-English speaking

The following should be submitted to the IRB for review and approval:

1. An English version of the informed consent document

2. The consent document translated into the desired language(s). Information should be provided on who performed the translation and the qualifications of the translator to perform the translation (for example, expertise in the foreign language such as a certified translator, native speaker or other evidence of fluency, and an appropriate background to understand the information in the consent form). The researcher may perform the translation if he/she is qualified in the language.

3. A back-translation of the translated consent document **or** certification from a translator that a back-translation of the consent was performed and found to be accurate. The back translation should be performed by a person OTHER than the original translator of the consent document. The name and qualifications of the back-translator should also be provided to the IRB.

Information should be provided in the study protocol about the process the investigator plans to use when obtaining consent from non-English speaking subjects. Unless the investigator is fluent in the participant's language, a qualified translator must be included in the consent process (e.g. the consent discussion) and must also sign the approved, translated consent form as a witness.

X OBTAINING CONSENT FROM THOSE WHO CANNOT SPEAK ENGLISH OR ARE ILLITERATE

Participants who are illiterate will also sign their mark on the signature line. When a study is expected to include illiterate participants, the investigator will describe during initial review how the consent process is to be carried out and will submit a "short form" consent document for approval (see below).

XI SHORT FORM WRITTEN INFORMED CONSENT DOCUMENT

A short form written consent document may be approved by the IRB for use when unexpectedly a research subject is to be enrolled who does not understand the language of the written consent. The Short Form process should not be used when the study plans or expects to enroll non-English speaking subjects.

The short form must state that all the required elements of informed consent have been presented orally to the participant or to the participant's legally authorized representative,

and the IRB must approve a written summary of what is to be said to the prospective participant. When this method is used, there must be a witness to the oral presentation. For participants who do not speak English, the witness must be conversant in both English and the language of the participant

- The person obtaining consent will sign and date a copy of the summary.
- The witness will sign and date both the short form and a copy of the summary.
- The participant (or the participant's legally-authorized representative) will sign and date the short form.

A copy of the signed and dated short form as well as a copy of the summary will be given to the participant or his/her legally authorized representative.

Harrisburg University
Institutional Review Board

INFORMED CONSENT
TEMPLATE for QUALITATIVE STUDIES

(language used throughout form should be at the level of a local 8th grade student)

Note to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study and the requirements of Harrisburg University of Science and Technology.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
- brackets indicate a text box where specific information is to be inserted
- bold lettering indicates sections which should be included
- explanations are provided in black italics, and examples are in red italics
- suggested questions to elucidate understanding are indented in black italics
- *instructions to researchers must not be included in your consent forms.*

TEMPLATE BEGINS ON THE FOLLOWING PAGE

Harrisburg University of Science and Technology

INFORMED CONSENT for Qualitative Studies

Name of Principal Investigator: [ ]
Name of Organization: [ ]
Name of Sponsor: [ ]
Title of Study: [ ]

Informed Consent form for: [ ]

Name the group of individuals for whom this informed consent form is written. Since research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "…….")

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

*THE FIRST SECTION OF IFC SHOULD INCLUDE A BULLETED HEADING THAT INCLUDES THE MOST PERTINENT *KEY* INFORMATION THAT WILL HELP A POTENTIAL PARTICIPANT DECIDE IF THEY WANT TO ENGAGE WITH THE REST OF THE STUDY. (See Above)*

Introduction

[ ]

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of

the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime, now or later.

(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.
This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the Research

[ ]

Explain the research question <u>in lay terms</u> which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee or IRB.

(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)

Type of Research Intervention

[ ]

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section, but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one-hour interview).

Participant Selection

[ ]

Indicate why you have chosen this person to participate in this research. People often wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)

- *Example of question to elucidate understanding: Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

[ ]

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services that you receive at this Centre will continue and nothing will change.
OR
The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures

[ ]

A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to…:)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

(Example 1 (for focus group discussions)
take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.
The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.
We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask….. ***We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.***
The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)
participate in an interview with [name of interviewer] or myself.
During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)
fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. Or, you may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.
If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration
[ ]

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks
[ ]

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for

refusing to take part in the interview."

OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits

[ ]

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole because of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).

Reimbursements

[ ]

State clearly what you will provide the participants with because of their participation. It is recommended not to use incentives beyond reimbursements for expenses incurred because of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

- ***Examples of question to elucidate understanding:***

Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?

Confidentiality

[ ]

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc])

<u>The following applies to focus groups:</u>
Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***<u>Example of question to elucidate understanding:</u>*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that we cannot guarantee complete confidentiality of information that you share with us in a group discussion? Do you have any more questions?*

Sharing the Results
[ ]

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You

may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community, and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)

Right to Refuse or Withdraw

[ ]

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part, or all, of the recording or note.

(Example: You do not have to take part in this research if you do not wish to do so. Choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Contact Information

[ ]

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local IRB that has approved the proposal. State also that the proposal has also been approved by any granting entity when appropriate.

(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]. This study has been reviewed and approved by Harrisburg University of Science and Technology Institutional Review Board which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee/IRB of (FUNDER), which is funding/sponsoring/supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Part II: Certificate of Consent

This section should be written in the first person and have a statement like the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

[ ]

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Signature of witness _____

OR

Thumb print of participant (in box at right)

Date _____
Day/month/year

Statement by the Researcher/Person Taking Consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. [ ]
2. [ ]
3. [ ]

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Harrisburg University
Institutional Review Board

INFORMED CONSENT TEMPLATE for CLINICAL RESEARCH & CLINICAL TRIALS

(language used throughout form should be at the level of a local 8th grade student)

Note to Researchers:

1. Please note that this is a template developed by the WHO to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study and the requirements of Harrisburg University of Science and Technology.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

- shaded rectangles indicate where specific information is to be inserted
- bold lettering indicates sections which should be included
- explanations are provided in black italics, and examples are in red italics
- suggested questions to elucidate understanding are indented in black italics
- *instructions to researchers must not be included in your consent forms.*

TEMPLATE BEGINS ON THE FOLLOWING PAGE

Harrisburg University
Institutional Review Board

INFORMED CONSENT for Clinical Studies

Name of Principal Investigator:
Name of Organization:
Name of Sponsor:
Title of Study:

Informed Consent form for:

Name the group of individuals for whom this informed consent form is written. Since research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for. *(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "…….")*

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

*THE FIRST SECTION OF IFC SHOULD INCLUDE A BULLETED HEADING THAT INCLUDES THE MOST PERTINENT *KEY* INFORMATION THAT WILL HELP A POTENTIAL PARTICIPANT DECIDE IF THEY WANT TO ENGAGE WITH THE REST OF THE STUDY. (See Above)*

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of

the words or concepts, that you will take time to explain them as you go along and that they can ask questions at any time, now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the Research

Explain <u>in lay terms</u> why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g., local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant Selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

➢ *Example of question to elucidate understanding: Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

➢ *Examples of question to elucidate understanding: If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [ ]

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example:. Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think, or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research, please talk to me or one of the other researchers. You may also report confidential concerns or complaints by using the "Ethics and Conduct related to HU Research" form, found by clicking the icon

Ethics and Conduct
Complaint Related to

You may also use the QR code to link the form. Hard copies of the form are also available on the IRB website under the Academic and research tab.

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example:. If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

If the protocol is for clinical research:
Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

For any clinical study (if relevant):
If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take about ……this much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)

B. Description of the Process
Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve….)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- *<u>Examples of question to elucidate understanding:</u> Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or

any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine does not work even as well as the old one. If, however, the medicine is not working, and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

- *Examples of question to elucidate understanding: Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period, he/she will be treated free of charge. There may not be any benefit for you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with because of their participation. It is recommended that incentives are limited to reimbursements for expenses incurred because of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example:. We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

- *Examples of question to elucidate understanding: Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- *Example of question to elucidate understanding: Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR
(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Contact Information

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee (AGENCY), which is funding/sponsoring/supporting the study. For Comments, Concerns or Complaints, please use the following Link or request a hard copy of the form, "Ethics and Conduct related to HU research" by clicking on the following icon.

Ethics and Conduct Complaint Related to

or QR code or by accessing the IRB website under the academics and research tab.

- *Example of question to elucidate understanding: Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement like the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. ***The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.***

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Signature of witness _____

OR

Thumb print of participant (in box at right)

Date _____
Day/month/year

Statement by the Researcher/Person Taking Consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

NON-COMPLIANCE WITH THE REQUIREMENTS OF THE HUMAN RESEARCH PROTECTION PROGRAM

I PURPOSE

In order to comply with 45 CFR 46.103(b)(5)(i) and 21 CFR 56.108(b)(2), HU will promptly report to the Office of Human Research Protection (OHRP) and US Food and Drug Administration (FDA) the necessary information that describes events affecting human research participant safety. The required reporting events include any serious or continuing noncompliance with federal policy or determinations made by the IRB.

II DEFINITIONS

1. **Allegation of non-compliance:** An assertion made by a person that must be proved or supported with evidence.

2. **Non-compliance:** Failure to follow the regulations; institutional policies governing human subject research; or requirements or determinations of the IRB. This may pertain to the principal investigator, the investigator's research staff, or any member of the human research protection program, including the IRB.

3. **Serious Non-compliance:** Non-compliance that creates an increase in risks to subjects, adversely affects the rights, welfare and safety of the research subjects or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance.

4. **Continuing Non-compliance:** A pattern of non-compliance that if allowed to continue is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.

Examples of non-compliance

The actions of anyone in the Human Research Protection Program may result in noncompliance:

- Performing human subject research without first obtaining IRB approval or an IRB declaration of exemption
- Deviating from or violating the provisions of an IRB-approved protocol
- Failing to secure IRB approval of a protocol due for periodic continuing review prior to its expiration date
- Permitting a protocol's IRB approval to lapse without stopping all research-related activities and submitting a Closing Progress Report to the IRB, or in

the event of an overriding safety concern or ethical issue such that it would be in the individual subject's best interest to continue study participation, arranging with the IRB to continue those activities

- Failure of the IRB to document in its meeting minutes or supporting documents protocol-specific findings supporting the IRB's determinations for waiver or alteration of the consent process, approval of research involving pregnant women, research involving prisoners, and research involving children

III REQUIREMENTS FOR REPORTING ALLEGATIONS OF NON-COMPLIANCE

Investigators and research staff are required to report any observed, suspected, or apparent non-compliance to the IRB. This refers to all non-compliance, not just serious or continuing noncompliance. All institutional members, research participants and others are encouraged to report any observed, suspected, or apparent non-compliance. Reports of non-compliance may also arise as a result of internal or external audits or as a result of IRB review. Investigator reporting requirements and procedures are described in policy (*Adverse Events or Unanticipated Problems).*

Reports of non-compliance must contain enough information to determine whether the report is sufficiently credible and specific so that potential evidence of non-compliance may be identified and acted upon.

IV IRB REVIEW PROCESS FOR REPORTS OF UNANTICIPATED PROBLEMS INVOLVING NON-COMPLIANCE

Handling allegations of non-compliance

All **allegations** of non-compliance are to be referred to the Chair of the IRB or designee. Within one week of receiving a report of potential non-compliance the Chair or designee will assign one or more members of the IRB to work with the Chair or designee to investigate the allegations contained in the report to determine whether any have a basis in fact. If they conclude that the allegations have a basis in fact, the process under "Handling non-compliance" will be followed. Otherwise, no further action is taken under this policy.

Handling non-compliance

a. All non-compliance (i.e. all allegations of non-compliance with a basis in fact and all self-reported non-compliance) will be reviewed by the Chair of the IRB or designee. The Chair or designee will evaluate the report and determine that the noncompliance is neither serious nor continuing or determine that the report might be serious or continuing non-compliance. A copy of all reports and a summary of the determinations of the IRB chair or designee will be provided to the IRB committee prior to the next scheduled meeting.

b. If the Chair of the IRB or designee determines the non-compliance is neither serious nor continuing, the Chair of the IRB or designee will determine whether any corrective actions are needed, and if so communicate those to the involved individual(s) and ensure all corrective actions are completed. The Chair or designee will work with the involved individuals to implement the corrective action plan. If the Chair or designee are unable to work with the involved individuals to implement the corrective action plan, the matter will be considered to be continuing non-compliance and the procedures in "Non-compliance that is determined to be serious or continuing" will be followed. All reports will be reviewed by the IRB at their next regular meeting.

c. If the IRB chair or designee determines that additional investigation is warranted, he or she may choose to designate an investigative committee to further assist with evaluation of the non-compliance. The investigative group may conduct interviews, review relevant records and materials, request an audit, solicit advice and opinion from consultants, and take any other reasonably necessary steps to determine whether the non-compliance is serious or continuing. The investigation, including preparation of any reports should be completed within 60 calendar days of initiation of the investigation. If circumstances clearly warrant a longer period, the Provost may approve an extension. The reason for the extension will be documented as part of the final report. This report will be provided to the convened IRB for their review.

d. If the IRB Chair, designee or investigative group finds the non-compliance is serious or continuing, the process under "Non-compliance that is determined to be serious or continuing" is followed.

Non-compliance that is determined to be serious or continuing

a. If the non-compliance is found to represent serious or continuing non-compliance, the results of any initial investigation and the report of non-compliance will be referred to the convened IRB for review and action.

b. The convened IRB will make the final determination of whether a report of noncompliance is serious or continuing in nature. For noncompliance found to be neither serious or continuing, the committee will determine whether any corrective actions are needed, and if so communicate those to the involved individual(s) and instruct the IRB coordinator to ensure all corrective actions are completed. If the IRB coordinator is unable to work with the involved individuals to implement the corrective action plan, the matter will be considered to be continuing non-compliance and the process described below will be followed.

c. If the convened IRB confirms that the non-compliance is serious or continuing, it may immediately suspend the research if it finds that doing so is necessary to eliminate apparent immediate hazards to the research subject. After

reviewing the steps already taken by the investigator, the IRB may also consider implementing one or more of the following actions:

- Suspension of the research
- Termination of the research
- Notification of current participants (required when such information might relate to participants' willingness to continue to take part in the research)
- Modification of the research protocol
- Modification of the information disclosed during the consent process
- Provision of additional information to past participants
- Requiring reconsenting current participants for ongoing participation
- Modification of the continuing review schedule
- Monitoring of the research or monitoring of the consent
- Obtaining more information pending a final decision
- Referral to other organizational entities such as legal counsel or Provost.
- Provision of additional recommendations to the Provost
- Other actions appropriate for the context of the event

Final Authority

The final authority rests with the IRB to determine (a) whether non-compliance is serious or continuing and (b) the development of an action plan to manage serious or continuing non-compliance.

The Provost has the final authority to make a determination of serious or continuing non-compliance. The Provost may constitute additional investigative groups with members drawn from appropriate programs across the University to further consider the non-compliance. This group will report its findings to the Provost in a time frame prescribed by the Provost.

V REPORTING

Any unanticipated problem reviewed by the IRB will be recorded in the minutes of the meeting at which it was reviewed. The minutes will reflect whether the problem involved noncompliance, risks to participants, is serious in nature, and/or is ongoing in nature.

Any substantive action taken by the IRB (defined as an action that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the AE in research) must be reported in writing to the Provost, the investigator's program lead, and the President.

Within 10 days the Provost will inform OHRP for federally funded studies, the FDA for studies involving drugs, devices, and biologics, the sponsor of the study and any other appropriate regulatory agencies of the action taken.

The Provost or designee, with assistance of the IRB Chair or designee and an IRB member, will report the institution's determination and findings to all appropriate entities within HSU and to relevant regulatory agencies. All correspondence will be filed in the IRB's protocol file.

HARRISBURG UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW BOARD

HUMAN SUBJECT RESEARCH USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

I PURPOSE

The HU IRB is responsible for ensuring compliance with the Health Insurance Portability and Accountability Act (hereafter referred to as the "Privacy Rule") when it acts as the privacy board for human subject research involving HU's or an external covered entity's (e.g., Pinnacle Health) protected health information (PHI).

The purpose of this policy is to define institutional and investigator Privacy Rule requirements for research involving human subjects, and the procedures the IRB will follow to ensure compliance with those regulatory requirements.

II SCOPE

This policy applies to all exempt and non-exempt human subject research (HSR) under the purview of the IRB that involves HU's and/or, when applicable an external covered entity's PHI.

It is important to note that many privacy board reviews conducted by the IRB involve non-HU protected health information or PHI. Therefore, investigators must also take steps to identify and to be compliant with any and all applicable external Privacy Rule policies/procedures prior to commencing any HSR approved by the IRB.

III DEFINITIONS

HIPAA/Privacy Rule means the minimum Federal standards (Health Insurance Portability and Accountability Act of 1996, specifically 45 CFR part 160 and subparts A and E of part 164) for safeguarding the privacy of individually identifiable health information. It includes the standards for an individual's privacy rights in order to enable them to understand and control how their protected health information (PHI) is used. Within the Department of Health and Human Services (DHHS), the Office for Civil Rights (OCR) is authorized to implement and enforce the Privacy Rule.

Protected Health Information (PHI) means individually identifiable health information, including demographic data that is collected from an individual, and meets all of the following criteria:

- is created or received by a health care provider, health care entity, health plan, public health authority, employer, life insurer, school/university, or health care clearing house; AND

- relates to past, present or future physical or mental health or condition of the individual; or the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; AND
- identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual; AND
- is transmitted or maintained in any form or medium, whether electronic, paper or oral (see 45 CFR 160.103).

Covered Entity means a health plan, a health care clearinghouse, or health care provider who transmits health information in electronic form. A covered entity is responsible for implementing Privacy Rule protections of PHI collected, generated, or stored under its auspices.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 164.501).

Authorization means permission to gain access to PHI. At HU, authorization for use and disclosure of PHI for research purposes is normally provided when a human research subject signs an informed consent document that contains an authorization section. Template authorization language can be found in Attachment A of this policy.

Workforce Member means employees, volunteers, trainees, and other persons whose work performance is under the direct control of a covered entity regardless of whether they are paid by the covered entity.

Use means to employ, apply, utilize, examine or analyze PHI maintained within the covered entity.

*Disclosur***e** means to share PHI with a person or organization outside the covered entity, unless the covered entity has designated a recipient as a "Business Associate."

Investigator is any individual involved in the design, conduct and/or reporting of research.

The HU Provost is the HU official who is responsible for the development and implementation of the policies and procedures required to comply with the Privacy Rule as defined by the Code of Federal Regulations, 45 C.F.R. 160, 162 and 164.

IV POLICY

HIPAA establishes the conditions under which PHI may be used and disclosed by investigators for research purposes. During the conduct of a research study, investigators may obtain, create, use, and/or disclose individually identifiable health information, which includes PHI. HIPAA permits investigators to use or disclose PHI for research only under the following circumstances and conditions:

- The subject has granted specific written permission through an authorization;
- There is documentation that the IRB or record has granted a waiver, partial waiver, or alteration of authorization requirements;
- The review of PHI is solely for purposes preparatory to research;
- The review of PHI involves only decedents' information;
- The PHI is de-identified in accordance with HIPAA standards, in which case the health information is no longer considered PHI; or
- The PHI is released in the form of a limited data set, with an executed data use agreement including provisions for the use and disclosure of the limited data set as defined below.

To ensure regulatory compliance and patient privacy, the IRB expects all investigators to adhere to the requirements described in this policy.

V PROCEDURES

A. Uses Preparatory to Research

An investigator may review PHI in medical records or elsewhere without subject authorization to prepare a research protocol (e.g., determining whether a sufficient number or type of records exists to conduct the research prior to IRB application) if the proposed research use meets all of the following provisions:

- The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes
- No PHI will be removed from the covered entity during the review, and
- The PHI that the investigator seeks to use or disclose is solely necessary for the research purpose.

<u>Preparatory Activities Involving HU PHI</u>
To meet the preparatory to research requirements, an investigator must request access from the IRB **<u>prior</u>** to the planned use. Any investigator who obtains this certification must be able to provide evidence that the use met the three above criteria upon request of HU Officials.

<u>Preparatory Activities Involving Non-HU PHI</u>

Prior to the preparatory to research access/use of PHI, an investigator must contact the appropriate research or privacy office of the covered entity to determine and then complete the appropriate preparatory to research requirements for that covered entity.

Minimum Necessary Standard

It is important to understand that uses of PHI for research without authorization (i.e., preparatory to research and under an authorization waiver) are subject to the "minimum necessary" standard - that is, the uses/disclosures must be no more than the minimum required for the described research purpose. Therefore, the investigator must demonstrate that the PHI to be accessed or used is the minimum necessary for preparing the research protocol and/or identifying potential subjects.

Recording PHI needed to contact potential subjects to obtain their written authorization (i.e., recruitment) is not covered by the "Preparatory to Research" provision and must only occur after IRB approval of the study that is in accordance with DHHS and FDA regulations.

B. Subject Recruitment – Partial Waiver of Authorization

To obtain a partial waiver for recruitment, an investigator must provide sufficient information in the study application to meet the following three criteria:

- The use or disclosure of the PHI for screening/recruitment purposes involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - An adequate plan to protect PHI identifiers from improper use and disclosure
    - An adequate plan to destroy the identifiers at the earliest opportunity, consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law, and
    - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule
- The screening/recruitment could not practicably be conducted without the waiver or alteration, and
- The screening/recruitment could not practicably be conducted without access to and use of the PHI.

Note that any subsequent use or disclosure of the same PHI requires written authorization or a separate waiver determination.

C. Written Authorization

Investigators are required to obtain written authorization from each human subject prior to the use or disclosure of the subject's individual PHI for research purposes unless the IRB, in its Privacy Board role, has granted a waiver. The purpose of the authorization is to inform an individual how his/her PHI and research information (collected or created) is to be used; who the information will be shared with; and to inform the individual of the right to access information about them that is held by HU and/or other covered entity.

All written authorizations must include certain elements and statements in order to be valid (45 CFR 164.508). A written authorization must include the following:

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner (e.g., medication list, problem list). It is not acceptable to state "entire medical record" unless the entire medical record is required to perform the research
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure
- The names of individuals, organizations, companies, and/or class of individuals to whom HU/covered entity officials and researchers (the covered entity) may disclose (share) the PHI, or who may use the subject's PHI in relation to the research study
- A description of the purpose(s) of the requested use or disclosure
- A signature block for signing and dating of the authorization by the individual or the individual's legally authorized representative (Note: only one subject signature is required to provide both authorization and consent)
- The authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure
- A statement of the subject's right to revoke authorization and how to do so, and, if applicable, the exceptions to the right to revoke the authorization
- A statement explaining whether non-research treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization. In addition, the authorization must specify whether a subject can still participate in research study if they don't provide authorization, and
- A statement of the potential risk that PHI will be re-disclosed and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the entities described in the above bullet.

The authorization must be written in plain language and included within the research informed consent form. To do this in accordance with HU requirements, a section entitled "Authorization to Use and Disclose Your Health Information" must be added as one of the last sections of the consent form.

Investigators must add study-specific information to the HU authorization template language or the IRB-approved template language of the appropriate covered entity. Approved authorization templates can be found on the HU IRB website.

FDA and DHHS regulations require that the IRB must review and approve all language included in the consent form. To facilitate this review, investigators should not deviate from currently approved authorization template language as described above, unless unavoidable. Any deviation proposed by the sponsor or study team must be submitted according to the IRB's current study application requirements for review and approval (e.g., submission of a separate copy of consent with all required authorization elements and statements labeled for review).

D. Exempt Research

Written informed consent is not required for research that is determined to be exempt from IRB review and approval in accordance with 45 CFR 46.101(b). However, the Privacy Rule still applies if that research involves PHI, and written authorization must be obtained from the subject unless the IRB grants a waiver as described below.

E. Waiver of Authorization and Required Documentation

Under the Privacy Rule, the IRB may waive or alter, in whole or in part, the Privacy Rule's written authorization requirements for the use and disclosure of PHI in connection with a particular research project. An investigator may seek a complete (full) waiver of the authorization requirements for some types of research.

For example, research conducted on existing databases or repositories that contain limited individual contact information, may qualify for a full waiver. The IRB may also approve a request that removes some, but not all, required elements of a written authorization (i.e., an alteration). For example, removing the element that describes the purpose of the requested use/disclosure of the PHI in cases where identification of the specific research study may affect the results of the study.

It is important to note that the waiver granted for a study applies only to the use of the PHI for that study, and no other studies. Any subsequent use or disclosure of the PHI obtained for a different research study from the waivered study must have a separate authorization. An exception may apply if the new research meets one of

the exceptions criteria under section 45 CFR 164.512(i) (e.g., waiver of authorization) or 45 CFR 164.514(e) (i.e., as a limited data set with a Data Use Agreement), but the IRB must make this determination that exception criteria are met. The investigator is not permitted to make this determination.

To approve a request for waiver or alteration of the requirement to obtain individual authorization, the IRB must determine (via information provided by the investigator in the IRB application) and document that the use meets all of the following three criteria:

- The use or disclosure of the PHI involves no more than a minimal risk to the privacy of subjects, based on, at least, the presence of the following elements:
    - An adequate plan to protect PHI identifiers from improper use and disclosure
    - An adequate plan to destroy the identifiers at the earliest opportunity, consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law, and
    - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration, and
- The research could not practicably be conducted without access to and use of the PHI.

IRB documentation (i.e., study approval or exemption letter) granting the waiver must include the following information:

- The identity of the approving IRB (i.e., HU IRB)
- The date on which the waiver or alteration was approved
- A statement that the IRB has determined that all the specified criteria for a waiver or an alteration were met
- A brief description of the PHI for which use or access has been determined by the IRB to be necessary in connection with the specific research activity, and
- A statement that the waiver or alteration was reviewed and approved under either normal or expedited review procedures

Generally, if a research protocol qualifies for a waiver of informed consent from the IRB, the research protocol may be eligible for a waiver of authorization under the Privacy Rule. However, the IRB must make the determination whether

waiver of authorization is appropriate. Investigators remain accountable, and have responsibility, for any PHI released under a waiver of authorization.

Investigators who conduct medical record reviews and secondary data analyses should be aware that the "not practicable without a waiver" standard requires substantive justification. For example, it may be practicable to get written authorization from 30 subjects who are current patients of the investigator. In contrast, it may not be practicable to obtain written authorization from 500 stroke patients seen at one hospital during the past ten years.

F. Accounting of Research Disclosures

The Privacy Rule gives individuals the right to receive an accounting of certain disclosures of PHI made by HU, the covered entity (see 45 CFR 164.528). This accounting must include disclosures of PHI that occurred during the six years prior to the individual's request for an accounting, or since the effective date of HIPAA (whichever is sooner), and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose (see 45 CFR 164.528(b) (3)).

To meet the accounting requirements, it is important to understand the difference between a use and a disclosure. Disclosures occur whenever PHI is shared with a person or organization outside HU, unless HU has designated a recipient as a "workforce member." During the conduct of research PHI is commonly "disclosed" to non-HU workforce members such as research sponsors, external collaborators, contract research organizations, and sample testing laboratories. "Use" means to employ, apply, utilize, examine or analyze PHI maintained within HU.

Accounting is required for certain "disclosures, not for "use" of PHI.

1.F.1 Applicable Research Disclosures

Investigators must account for all disclosures of PHI under a waiver (partial and full) of authorization granted by the IRB or disclosures of decedent PHI for research where no authorization on behalf of the individual has been obtained.

Among the types of research disclosures that are exempt from this accounting requirement are:

- Research disclosures made pursuant to an individual's written authorization;

- Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

PHI that has been obtained through a review preparatory to research (as defined in the regulations) is not to be removed from the covered entity (i.e., disclosed) by the investigator in the course of the review. Therefore, it is also not subject to the accounting requirements.

1.F.2 Single Disclosure Per Individual for Research Involving Less Than 50 Subjects

As a general rule, the following information must be maintained and provided to an individual or their authorized representative upon request:

- The date of the disclosure;
- The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
- A brief description of the protected health information disclosed; and
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of the applicable written request for a disclosure, if any.

1.F.3 Multiple Disclosures Per Individual for Research Involving Less Than 50 Subjects

If there have been multiple disclosures to the same person or entity (such as multiple disclosures of that person's information to a researcher or sponsor) during the "accounting period" the person is requesting, the following information may be provided:

- The information required above for the first disclosure during the accounting period;
- The frequency, periodicity, or number of the disclosures made during the accounting period; and
- The date of the last disclosure during the accounting period.

1.F.4 Disclosures for Research Involving 50 or More Subjects

In addition, for research disclosures of PHI without the individual's authorization pursuant to 45 CFR164.512(i), and that involve at least 50 individuals (such as with research databases), the Privacy Rule allows for a simplified accounting of such disclosures. Under this simplified accounting provision, covered entities may provide individuals with the

following for disclosures where the PHI about the individual was (or may have been) included:

- The name of the protocol or other research activity;
- A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
- A brief description of the type of PHI that was disclosed;
- The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
- The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
- A statement that the PHI of the individual may or may not have been disclosed for a particular protocol or other research activity.

1.F.5 Required Logging of Research Disclosures

Investigators are responsible for logging disclosures described above.

A copy of the required log information (Sections 1.F.2, 1.F.3, 1.F.4) must be maintained for audit purposes by the investigator for at least six years and securely stored to protect confidentiality.

1.F.6 Individual Requests for Accounting of Disclosures

All individual requests for an accounting of disclosures will be directed to the Provost. The Provost will be responsible for providing the required information in accordance with all applicable HU policies and requirements. If an individual requests additional information about disclosure of their PHI for research purposes after receiving their initial accounting, the applicable investigator will be responsible for providing as much additional information about the disclosure as available to the Provost.

The documentation of disclosures and related information must be maintained for at least six years from the completion of the research involving the disclosure of PHI.

G. De-Identified Data

Data that may be considered "de-identified" under HHS and FDA

regulation may not be considered "de-identified" under the Privacy Rule. For example, under HHS regulations (45 CFR 46.101(b) (4)) an investigator can record data such that the subjects "cannot be identified, directly or" indirectly "through identifiers linked to the subjects." Under this scenario, individual subject data collected by the investigator containing a zip code could be considered "de-identified," but not de-identified under the Privacy Rule.

Using improperly de-identified data for research can constitute non-compliance. Therefore, investigators who plan to conduct research involving "de-identified data" are encouraged to consult with the HIPAA & Privacy Compliance Office or the IRB Office prior to initiation of such research to ensure that their proposed data set(s) meet the Privacy Rule requirements.

To be considered "de-identified" under the Privacy Rule, EITHER: all of the following 18 identifiers of the individual, their relatives, employers, or household members must have been removed from the individual's data set by an individual that is not a member of the study team (e.g., medical records official, administrator of a database):

1. Names (including the patient's name and names of other individuals connected to the patient)
2. Geographic subdivisions smaller than a state (zip code, street address, etc…)
3. All elements of a date (except year) including birth date, admission date, discharge date, date of death, and all ages over 89)
4. Telephone numbers
5. Fax numbers
6. E-mail address
7. Social security number
8. Medical record number
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers including license plates
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers including fingerprints and voice prints
17. Full face photographic (or comparable) images
18. Any other unique identifying number, characteristic, or code unless otherwise permitted by the Privacy Rule for re-identification, and

HU does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

OR

The data is grouped in such a way that a qualified statistician using accepted analytic techniques concludes that the risk of identification based on the information in the data set is substantially limited, and that if the information is used alone or in combination with other reasonably available information, it does not identify an individual subject (e.g., aggregate data) [45 CFR 164.514(b)].

Health information that meets this definition of "de-identified" is not considered PHI; therefore, the Privacy Rule permits investigators to use and disclose de-identified data without obtaining authorization and without further restrictions on use or disclosure.

H. Limited Data Sets and Data Use Agreements

A "limited data set" is defined in the Privacy Rule as a limited set of PHI that may be disclosed to an outside party without a subject's authorization if certain conditions are met. First, the purpose of the disclosure may only be for research, public health or health care operations. Second, the person receiving the information must sign a data use agreement with HU prior to being given the limited data set containing HU PHI.

Specifically, as it relates to the individual or his or her relatives, employers or household members, all of the following 16 identifiers must be removed in order for health information to be considered a limited data set:

1. Names (including the patient's name and names of other individuals connected to the patient)
2. Street addresses (other than town, city, state and zip code)
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical records numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate license number
11. Vehicle identifiers and serial numbers, including license plates
12. Device identifiers and serial numbers
13. Web universal resource locators (URLs)

14. Internet protocol (IP) address numbers
15. Biometric identifiers (including finger and voice prints)
16. Full face photographic (or comparable) images

The health information that may remain in the disclosed information of a limited data set includes:

- Dates such as admission, discharge, service, date of birth, date of death
- City, state, five digit or more zip code
- Ages in years, months or days or hours

It is important to note that the information in the limited data set is not considered de-identified and therefore is still subject to the requirements of the Privacy Rule.

A data use agreement must meet the following standards specified in the Privacy Rule:

- Establish the permitted uses and disclosures of the limited data set
- Identify who may use or receive the information
- Prohibit the recipient from using or further disclosing the information, except as permitted by the agreement or as permitted by law
- Require the recipient to use appropriate safeguards to prevent a use or disclosure that is not permitted by the agreement
- Require the recipient to report to the covered entity any unauthorized use or disclosure of which it becomes aware
- Require the recipient to ensure that any agents (including a subcontractor) to whom it provides the information will agree to the same restrictions as provided in the agreement, and
- Prohibit the recipient from identifying the information or contacting the individuals whose PHI is included in the limited data set.

The limited data set provisions of the Privacy Rule also require HU to take reasonable steps to cure any breach by a recipient of the data use agreement. That is, if HU determines that data provided to a recipient is being used in a manner not permitted by the agreement, it must work with the recipient to correct this problem. If these steps are unsuccessful, HU must discontinue disclosure of PHI to the recipient under the data use agreement and report the problem to the Office of Civil Rights, Department of Health and Human Services ("DHHS").

Research Involving "External" Limited Data Sets

HU investigators who wish to conduct HSR using a limited data set from an external institution must have the external institution's Data Use Agreement reviewed and signed by the Provost to ensure that it meets Privacy Rule and HU

requirements prior to receiving the data from the external/collaborating institution.

Investigators are required to submit a copy of any data use agreement to the HU IRB as part of a study's initial application process, as well.

I. Non-compliance and Privacy Breaches

Any investigator who is aware of potential non-compliance with this policy must immediately report it to the IRB Chair, who will notify appropriate institutional officials (including the Provost) and facilitate review of the matter under applicable institutional policy.

The Privacy Rule requires that HU and/or applicable covered entity review and address any potential privacy breach within 60 days of any Workforce Member discovering the breach. Therefore, prompt reporting of any Privacy Rule compliance issues is essential to meet this requirement.

VI RESPONSIBILITIES AND AUTHORITIES

A. The IRB is responsible for:

- Approving template authorization language
- Reviewing and approving authorization language contained within a consent document
- Reviewing and approving requests for a waiver, partial waiver or alteration of the Privacy Rule's authorization requirements, and
- Reviewing, in coordination with the Provost, non-compliance allegations involving Privacy Rule requirements.

B. Investigators are responsible for:

- Providing complete and accurate information to the IRB regarding the proposed use, creation and disclosure of PHI
- Meeting preparatory to research requirements prior to accessing PHI
- Complying with account of disclosures logging requirements
- Ensuring that each human subject receives a signed copy of his/her authorization, and
- Properly storing signed authorizations for at least six years from date of signature or the expiration date contained in the authorization.

VII RECORDS

Signed authorizations must be retained by the investigator (or HU in absence of investigator) for six (6) years from the date of signature or when it was last in effect, whichever is later.

VIII REFERENCES

45 CFR Part 160
45 CFR Part 164

APPENDIX A

HUMAN USE TEMPLATE AUTHORIZATION LANGUAGE

** Please insert template language as the last "section" of your informed consent document. Provide study specific information for all highlighted sections and delete all instructions before submitting to IRB for review. **

Authorization to Use and Disclose Your Health Information

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. **Please read this section of the consent form carefully.**

If you sign this document, you give permission to (insert name of PI) and his (or her) HU/[insert name of covered entity] research team to use or disclose (release) the following protected health information: *(List PHI to be used, created or disclosed for this study in a specific and meaningful way.)*

- Your medical records for past medical conditions and medications related to your heart health
- All information (research records and medical records) created during your participation in this research study
- All information related to illness or hospitalizations that occur during your participation in this study

The research team needs this information to conduct the CDE Trial. The CDE Trial is a study to test whether a device called an XYZ can increase the likelihood of survival in patients at risk of a stroke or heart attack. (*Should include title and purpose of research study*)

Disclosure of your protected health information

If you sign this form, the researchers may share your health information during the conduct of the study with:

- Non-HU/[insert name of covered entity] researchers or organizations working with HU/[insert name of covered entity] researchers: insert names/organizations here
- Law enforcement or other agencies, when required by law
- Harrisburg University's Institutional Review Board, which oversees our research

- The sponsor (the organization paying for) of this research study: insert name(s) here
- Representatives of government agencies (i.e. Food and Drug Administration and the Office of Human Research Protection)
- Other authorized Harrisburg University and [insert name of covered entity, if applicable] Officials who oversee research and clinical care
- (*List all that apply - Data Coordinating Centers, Data Safety Monitoring Boards, consultants, etc...who will/may be given access*)

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write to: Dr. ABC at [insert name of covered entity], [insert address].

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

Right to refuse to sign this Authorization

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at [insert name of covered entity] will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. **I agree to participate in this research and authorize the use and disclosure of my protected health information for this study.** I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

_____

Signature of Person Obtaining Consent and Authorization

_____

Date

_____

Printed Name of Person Obtaining Consent and Authorization

_____ _____

Signature of Legally Authorized Rep. Date

_____

Description of LAR's Authority (add highlighted section if LAR approved by IRB)