THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board Policy

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PART 1: The Institutional Review Board

1.1 Mandate

The Institutional Review Board of the University of Tennessee at Chattanooga (UTC) operates under the US Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects: Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). The IRB also is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report. For more information on these documents and the historical evolution of these principles, please consult Appendix A.

The mission of the IRB is to ensure that vital university research can be conducted in full compliance with both the letter and the spirit of regulations designed to protect the rights and welfare of human subjects. The IRB also monitors research to ensure that human subjects are protected from undue risk and from deprivation of personal rights and dignity. This protection is assured by consideration of three principles that are the basis of ethical research:

1. That voluntary participation by the subjects, indicated by free and informed consent, is assured by the investigators;

2. That an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subject; and

3. That there are fair procedures and outcomes in the selection of research subjects.

The IRB Chair and Committee share authority over all IRB policy and procedure in collaboration with the IRB Director and the Institutional Official.

1.2 Institutional Assurance of Compliance

To certify that UTC complies with these federal regulations, the Office of Research Integrity (ORI) has filed an Institutional Assurance of Compliance with DHHS Regulations with the Office of Human Research Protections (OHRP). The assurance includes a statement of ethical principles and institutional policy, a detailed identification of UTC's responsibilities, ORI's general procedures, the Institutional Review Board's policies and procedures, and the general responsibilities of the research investigator. The Assurance number assigned to UTC is FWA00004149 and the IRB Registration Number is 0002572. This Assurance and Registration is maintained regularly by the Office of Research Integrity. The IRB Director is designated as the Human Protections Administrator and the Vice Chancellor of Research as the Signatory Official (Institutional Official) on the Institutional Assurance of Compliance.

1.3 Jurisdiction

UTC's IRB reviews all research involving human subjects regardless of sponsorship. All faculty and staff (both full-time and part-time) using human subjects or identifiable, private information about human subjects to conduct research within the course and scope of their duties are required to have prior approval from the IRB *before research is initiated*. Projects must be approved prior to data collection regardless of whether the research is funded and regardless of the source of funds. This policy also applies to students

whose research is conducted under the advisement of a faculty member. *All research proposals must be reviewed by the IRB and no individual other than the IRB Chair or his or her designee may exempt a proposal from review.*

Research is defined as: "…A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A Human Subject means: "A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

A Clinical Trial is "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on health-related biomedical or behavioral outcomes.

1.4 Composition of the Board

The IRB is composed of:

1. At least 5 members of sufficiently diverse backgrounds, including consideration of race/ethnicity, gender, age, professional expertise, and cultural backgrounds, to promote complete and adequate review of research activities commonly conducted by the university;

2. Persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable law, and professional standards;

3. At least one member whose primary concern is in a scientific area;

4. At least one member whose primary concern is in a non-scientific area;

5. A member who is not affiliated with the institution or an immediate family member of a person who is affiliated with the institution; and

6. The IRB Director, who serves as a non-voting, ex-officio member.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. When needed, an IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB Committee. For example, when research involves vulnerable subjects (i.e., children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons) the IRB will ensure that at least one board member has expertise in the area or will invite an outside individual to assist in the review. Invited persons provide information and feedback to the IRB; however, they may not vote with the IRB and are not counted in determining whether a quorum is present.

The IRB Chair is selected by the IRB Director with confirmation by the Vice Chancellor for Research (the Institutional Official). The IRB Chair is expected to serve a four-year term. The IRB Chair may be reappointed to additional terms at the discretion of the Institutional Official.

The IRB Chair may resign at any time by submitting a letter of resignation to the IRB Director and Institutional Official. The Institutional Official may remove the IRB Chair from the committee if the Chair is unable to meet his/her responsibilities.

IRB members are selected by the IRB Director and the IRB Chair, who may seek input from past or present IRB members, department heads, deans, and/or the Institutional Official. Board members serve three-year terms. There is no maximum time limit that a board member may serve. Reappointments to additional three-year terms are made at the discretion of the IRB Director and Institutional Official. Ideally, the IRB Director and Institutional Official will seek to ensure that the Chair of the IRB and at least two people on the Board have prior service with the IRB at UTC or another institution.

1.5 Responsibilities of the IRB

The IRB will:

1. Review all content included in the IRB application and supporting documents to ensure that responsible, ethical research is being conducted with minimal risk. The IRB Director, the IRB Chair, and/or the IRB Committee members have the authority to request additional information in all areas if necessary to ensure an informed review of the proposed research project;

2. Review and have authority to approve, exempt, require modifications (to secure approval), or disapprove all research activities covered by this policy;

3. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, for all research sponsored by funding agencies adhering to the pre-2018 regulations (e.g. have not adopted the Common Rule, for example, Department of Justice), and all research requiring full board review.

4. Have authority to observe or have a third party observe the consent process and the research;

5. Review proposed changes in research activities to ensure that changes in approved research during the period for which IRB approval has been given have not been initiated without IRB review and approval;

6. Require that information given to subjects as part of informed consent is in accordance with policy;

7. Require or waive documentation of informed consent;

8. Notify, in writing, investigators and the institution of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing;

9. Monitor additional safeguards when vulnerable subjects (minors, prisoners, individuals with impaired decision making capacity and economically or educationally disadvantaged persons) are involved in the research in order to protect against coercion or undue influence;

10. Conduct its review of research (except when an exempt or expedited review procedure is used) at convened meetings where a quorum of the IRB is reached.

11. Approve research only with the concurrence of a majority of those members in attendance;

12. Report to the institution and OHRP any continuing or serious matters of non-compliance by investigators with the requirements and determination by the IRB; and

13. Have authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.

1.6 IRB Records

The Office of Research Integrity will maintain:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, approved advertising or other solicitations for subjects, progress reports and injuries to subjects;

2. Minutes of all 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 controversial issues and their resolution;

3. Records of continuing review activities;

4. Copies of all correspondence between the IRB and investigators;

5. A list of all IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant);

6. A compendium of written procedures; and

7. Statements of significant new findings provided to subjects.

Records shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

PART II: Categories of Review and the Review Process

Specific criteria for IRB approval of research are discussed in more detail in the following sections; however, the following elements are central to IRB decisions. The IRB will consider whether:

1. Risks to subjects are minimized;
2. Risks are reasonable in relation to anticipated benefits;
3. Selection of subjects is equitable;
4. Informed consent is sought from each subject; and
5. Informed consent is appropriately documented.

There are four categories of review for projects involving human subjects in research settings:

1. Exempt
2. Expedited
3. Full Board Review
4. Modifications or Continuing Renewals

Exempt Review: Minimal risk research that falls into one of the federally-defined exempt categories will undergo review by the IRB Administrator in the Office of Research Integrity and is exempt from further review. The Exempt categories are defined in Appendix B of this document.

Expedited Review: Minimal risk research that does not qualify for exempt review and falls under one of the expedited categories will undergo review by two designated reviewers who are IRB members. Expedited categories are defined in Appendix C.

Full Board Review: Studies that involve more than minimal risk to the subjects or do not fall into one of the exempt or expedited categories require review by the full IRB committee membership. Please note that the types of research conducted at UTC rarely require full board hearings. In most cases, expedited review is possible.

The IRB Committee or the designated reviewers must approve any IRB application before the proposed research may proceed, and the investigator must receive a letter from the Office of Research Integrity confirming this decision. There is no such thing as an emergency exemption or retroactive approval, and no university official other than the IRB Committee may grant approval.

The following sections outline the application process for all categories of review, the process for exempt, expedited, and full board reviews, and the mechanisms for requesting modifications and for continuing review.

2.1 The Application Process

To begin an IRB application, the investigator completes the IRB Protocol Application Form. This form requires information about the purpose/objectives of the research; background and rationale for the study; the subject population; methods/procedures; incentives; risks and benefits; and privacy/confidentiality. The completed IRB Protocol Application Form, consent forms, and any special attachments (including questionnaires or surveys if applicable) must be submitted to the Office of Research Integrity via DASH Research IRB. Upon submission within DASH Research IRB, the IRB will review and determine the appropriate level of review (and category, if applicable). Application forms and DASH Research IRB User Guides can be found at the IRB website (http://www.utc.edu/irb).

Communication between the Office of Research Integrity and the investigator during the review process will occur within DASH Research IRB.

IRB applications may be submitted at any time (i.e., there are no deadlines or specific times that applications are accepted). DASH Research IRB submission is required. If the IRB determines that a full board review is required, the protocol will be added to the next (monthly) IRB meeting agenda and will be reviewed by the full board.

2.1.a Additional Special Requirements or Attachments to the Application

If the study involves any of the following items, they must be included in the DASH Research IRB submission.

a. IND (Investigational New Drug) Number and Investigator's Brochure

When a study involves use of an unapproved drug, or an approved drug for a new use, the investigator must submit an IND number obtained from the FDA and one copy of the Investigator's Brochure for the drug, which provides background information such as information from animal research and toxicity data. *If an IND is included, investigators will need to reach out to the Office of Research Integrity about applying through the University of Tennessee Health Science Center's (UTHSC) IRB office.*

b. IDE (Investigational Device Exemption) Number and Investigator's Brochure

When a study includes an unapproved device or an approved device for a new use and a "significant risk" devise is involved, the investigator must submit an IDE number obtained from the FDA and one copy of the Investigator's Brochure for the device. If the investigator believes that the device poses a non-significant risk, FDA regulations allow the option of requesting a "non-significant risk" IDE determination from the local IRB. The Investigator must submit this request to the IRB with an explanation of why the study should be considered of non-significant risk and other supporting information. This request and justification should be presented separately or distinctly from the application for approval of the protocol. The IRB will make a determination based on the criteria described in the FDA "Guidance on Significant and Non-Significant Risk Device Studies". Depending on the circumstances of the study, additional safety or liability assurances may be required on an individual, case-by-case basis. *If an IDE is included, investigators will need to reach out to the Office of Research Integrity about applying through UTHSC's IRB office.*

c. Data Use Agreement and/or Data Security Plan.

When a study will utilize data subject to terms and conditions set forth by the data provider or custodian, the agreement and related documents must be submitted as attachments. Confidentiality measures and data security protections defined in the agreement and related documentation can be referenced in the IRB Protocol Application Form in response to the questions corresponding with these topics.

d. Collaborative Research

Collaborative research projects involve more than one institution. The oversight requirements for non-exempt and exempt research, and research conducted with international collaborators, differ as follows:

Non-exempt research. Collaborative research projects that require expedited or full board review and are located in the United States typically must use a single IRB (sIRB). In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy even though the review is conducted by a single entity. Identification of the sIRB of record will be made by the IRB Directors and Principal Investigators from the collaborating organizations in accordance with NIH sIRB policies and guidance or The Common Rule sIRB policy and guidance, as appropriate. This may require execution of an authorization agreement. If

the other institution is the sIRB of record, UTC will require a copy of the IRB application and approval letter from the collaborating institution and will review to ensure agreement with the approval. In those cases, UTC will be the relying institution. If UTC is the sIRB of record, the IRB study will be reviewed as usual and a reliance agreement will be executed with the relying IRB.

Exempt research. The UTC IRB is responsible for ensuring that research conducted by UTC personnel receives the appropriate level of oversight. For collaborative projects that qualify for exemption from the Common Rule (see section 2.1.1), the lead Principal Investigator should submit an application for an exemption determination to their institution's IRB. If the initial exemption determination is being made by a collaborator's IRB, the UTC IRB requires a copy of the IRB application and approval letter to confirm the exemption determination. In some cases, the UTC researcher(s) may be required to submit a separate exempt application to the UTC IRB (e.g., if the data collection instruments and/or methods will differ across collaborating institutions). UTC will not enter into sIRB authorization agreements for any research determined to be exempt; in this scenario, the regulations related to sIRB use are not applicable.

Research with international collaborators. Such projects can have different requirements and will be reviewed on an individual basis to determine review requirements. If an sIRB approval is appropriate, the guidelines listed above are applicable.

d. Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collection sheets must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

e. Advertisements/Notices/Recruitment Flyers

Any recruitment materials, including flyers, social media posts, emails, and phone scripts, should be included as attachments.

f. Financial Conflict of Interest

All investigators, including faculty, staff or students, listed on an IRB study protocol, will be required to update their Conflict of Interest disclosures through DASH Research COI unless their disclosure has been updated within the past 30 days.

g. Funded Research Proposal Narrative

If the research is funded, include a copy of the research proposal narrative within the 'Study Funding Sources' page of the DASH Research IRB application.

h. Permission/Approval for Research Activities Conducted at an Outside Entity

If research will be conducted outside of the university, documentation must be submitted from the entities giving the researcher permission to conduct the research at their facility.

2.2 Application Processing & Review

2.2.a. Exempt Review Process

Typically, a two week review process is required from the time the application is received by the Office of Research Integrity for Exempt applications. The application will be reviewed to ensure that the research qualifies for an exemption designation review. If the research meets exemption criteria, an exemption

designation letter will be sent to the principal investigator. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, or confidentiality of research records), the principal investigator will receive an Action Form. The Action Form will outline the concerns that must be addressed in order to continue the review process. It also may indicate that the research does not qualify as Exempt and indicate that Expedited or Full Board Review will take place.

2.2.a.i Limited IRB Review of Exempt Studies

Limited IRB was added by the Final Rule and is relevant to certain exemption categories that occurred due to the revisions of July 19, 2018 (Categories 2, 3, 7, and 8). Limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data. In a limited IRB review certain categories can be exempt, even when identifiable information might be sensitive or potentially harmful if disclosed.

Limited IRB review is required for the following:

Exempt Category 2 (educational tests, surveys, interview or observations of public behavior) – When the information is recorded by the Investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

Exempt Category 3 (benign behavioral interventions) – When information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

Exempt Category 7 and 8 (broad consent)* - When investigators plan to store, maintain or use identifiable private information or identifiable specimens collected for non-research purposes and the information/specimens are obtained with a broad consent process.

*UTC is not participating in Broad Consent.

In order to ensure appropriate protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justifications for needing identifiers in order to conduct the research
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to the study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place (physical safeguards for paper records, technical safeguards for electronic data, secure sharing or transfer of data outside the institution, if applicable)
- The potential risk for harm that would occur if the security of the data was compromised

Limited IRB reviews will be performed by the IRB Chair.

2.2.b Expedited Review Process

The review process for expedited review typically takes about two to three weeks from the time the application is received by the Office of Research Integrity (provided there are no modifications or clarifications needed to the application).

An expedited review will normally be conducted by two IRB committee members who will be assigned by the Office of Research Integrity. Expedited reviews will be rotated among IRB committee members based on expertise and workload. Under certain circumstances, the IRB Chair alone may conduct the expedited review. If reviewers indicate approval at the expedited level, the Office of Research Integrity will send a letter of approval to the principal investigator or the student and faculty advisor noting that the research has been approved.

If the information on the application seems incomplete or either reviewer requests changes or clarifications, the applicant will receive an Action Form outlining the modifications that must be addressed before continuing the review process. If the investigator does not agree with the comments of the reviewer(s) or feels that any suggested changes conflict with the investigator's vision of the research project, they may request a hearing by the full board. Likewise, the IRB Director, the IRB Chair or any reviewer may refer the application to the full board for review. If the reviewers or the IRB Chair have concerns about approving an application (e.g. eligibility for expedited review, risks being greater than minimal, etc.), they must refer it to the full board for a hearing. An application cannot be withheld at the expedited level without a full board hearing.

2.2.c Full Board Review Process

The IRB committee has a standing monthly meeting unless there is no committee business to discuss. The full IRB membership will review applications during their meetings. A study requiring full board review will be added to the soonest upcoming meeting once any modifications indicated in the pre-review Action Form are returned by the investigator to the IRB.

A quorum is defined as a majority of the IRB membership present at a convened meeting, including a member who is a nonscientist. A quorum is required to review and vote on IRB applications.

Votes are taken and recorded at the convened meeting after a discussion of the application. If the majority of the members present vote to approve the application it is considered approved at the meeting. The Office of Research Integrity will promptly notify the investigators in writing of the decision, via DASH Research IRB communications. If the IRB committee has unanswered questions or concerns about the proposal, a majority vote may result in a request for additional information, clarification, or changes to the application. The Office of Research Integrity will issue an Action Form explaining the requested revisions discussed in the meeting (these comments also will be reflected in the IRB Committee minutes). The principal investigator must then address a response and/or revise the application to obtain approval. The investigator also may request to meet in person with the Committee.

Votes are taken and recorded at the convened meeting after a discussion of the application. A majority vote may result in one of the following actions:

- *Approval:* Approval indicates that the research meets all criteria for approval as written, as well as any applicable subpart requirements, and may proceed as of the date of approval.

- *Approval pending changes:* When the full board determines that all criteria for approval and applicable subpart requirements will be met after very specific, directive changes are made, the full board can approve the research pending these changes being made and resubmitted.

- *Request for modifications in order to secure approval:* If the full board determines that modifications to the research are needed before the criteria for approval or subpart requirements can be met, the research cannot be approved. The full board should identify the required changes in a specific and meaningful way that is actionable for the research team. The full board's communication must include the justification or basis for the modifications.

- *Disapproval:* Disapproval indicates that the criteria for approval are not met. The full board must communicate the reason for the disapproval and allow an appeal process.

If revisions or requests for clarification are required for approval, The Office of Research Integrity will issue an Action Form explaining the requested revisions discussed in the meeting (these comments also will be reflected in the IRB Committee minutes). The principal investigator must then address a response and/or revise the application to obtain approval. The investigator also may request to meet in person with the Committee.

On very rare occasions, the IRB may encounter major difficulty in making a risk/benefit assessment, and an outside reviewer may be asked to consider the application and provide input based on their specific expertise; however, this reviewer will not be allowed to vote. The IRB Committee also may request the principal investigator to attend a full board meeting to discuss or clarify issues with the application.

IRB Studies approved under the Full Board review process are approved for one year from the approval date, and a Continuing Review must be conducted annually to maintain approved status of the study.

2.3 Modifications and Continuing Reviews

2.3.a Modification Requests

Modifications to IRB protocols will be reviewed and approved at the level of original review (i.e. Exempt or Expedited), unless a modification would increase the level of risk or move a protocol up in level of review (from Exempt to Expedited, or from Expedited to Full Board). **Changes to the purpose or research questions or that would move the study to a higher level of review will require a new protocol application submission, rather than using the modification process.**

Minor changes have no impact upon the original goals and protocols outlined in the original application. Minor changes include those that do not adversely alter the overall harm-benefit profile of the study or would not potentially affect the willingness of current subjects to remain or enroll in the study. Examples include: change of project title, minimal changes in wording of a survey instrument, minor grammatical changes to an informed consent and/or child's assent form, addition or deletion of collaborators and/or co-PIs, change in student advisor, or end date extensions.

Major changes modify the research methods or otherwise impact the experience of participants. Examples might include changes in: sampling population or additional sites, survey instruments,

interview protocols, administration of a treatment of any kind, and/or the informed consent process. Change in Principal Investigator is also considered a major change. Any research, by definition, that increases the level of risk to the participant relative to the initial application MUST assume that the changes are major.

Any changes to an approved study must be approved by the IRB before implementation. The investigator will submit a Modification within DASH Research IRB outlining the requested changes and include revised documents, as applicable. Once the changes are approved, the investigator will receive an email notification of the approval from DASH Research IRB. The IRB Administrator will contact the investigator in writing if the changes outlined are not acceptable, or if the changes are substantial and require an entirely new IRB application.

Table 1 – Review of modifications by initial review level and modification level

	Original Review Level		
Modification level	**Exempt**	**Expedited**	**Full Board**
Minor	Reviewed by IRB Administrator	Reviewed by IRB Administrator	Reviewed by IRB Chair
Major	Reviewed by IRB Administrator	Reviewed by IRB Chair	Reviewed by Full Board

Application forms and DASH Research IRB User Guides can be found at the IRB website (http://www.utc.edu/irb).

Modification requests can be submitted at any time (i.e., there are no deadlines or specific timeframes for submission). DASH Research IRB submission is required.

2.3.b Study Closures, End Date Extensions, and Annual Reviews

Continuing Reviews are used to extend the end date of approved protocols and to conduct Annual Reviews for studies that require them. Continuing Reviews are used for the following cases:

1. Exempt and Expedited protocol approval will expire on the end date indicated by the investigator on their IRB Protocol Application Form. If the investigator wishes to extend the end date, they must submit a Continuing Review request through DASH Research IRB. If approved, the end date will automatically be extended by one year unless the investigator requests a specific end date in a note within the Continuing Review request.
2. Any investigator completing the work on their approved protocol may initiate a Continuing Review to close out their study ahead of the original end date.
3. Full Board protocols require a Continuing Review annually. The approval for full board protocols will expire one year after initial approval or the last continuing review.
4. Rarely, the IRB reviewers will flag an Expedited protocol as requiring continuing review annually. In such cases, the investigator will be given an explanation for the requirement of the annual review, and the approval on that protocol will expire one year after the initial approval or the last continuing review.

The process for Continuing Review is the same for all four cases: the investigator will create a Continuing Review in DASH Research IRB and follow the prompts to answer questions about the status of the study

and any research milestones achieved. Continuing Reviews to extend the end date or end the protocol early will be approved administratively by the Office of Research Integrity.

> For those projects requiring an annual review, the investigators are required to submit a "Continuing Review" within DASH Research IRB at least four weeks before the anniversary date. The DASH Research IRB system sends out renewal reminders six to eight weeks before the study expires informing the investigator that if the project will continue into the next year, a "Continuing Review" must be completed and approved prior to the expiration of the approval date. It is, however, ultimately the investigator's responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. **If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal and university policy.**
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> IRB applications that were originally approved as a result of a Full Board Hearing require a hearing of the full committee for renewal. The Office of Research Integrity will schedule these meetings.

When Continuing Reviews are approved, the Study will be updated with a new end date, one year from the approval of the Continuing Review.

2.4 IRB Approval Involving Externally Funded Applications

Investigators are encouraged to submit IRB applications for approval prior to securing funding; however, if there is insufficient time to do so, proposals may be submitted with the assurance that IRB approval will be sought and received prior to pursuing any research related activities. In these cases, the investigator must articulate the specific portion of the grant that will require IRB approval in the funding application and provide an anticipated start date for these activities. For example, an investigator might apply for a grant with a funding cycle that begins in January; however, there are no activities that require human subjects' approval until June. From January to June the investigators might be engaged in planning activities, drafting questionnaires, or offering direct services. In these types of cases, the investigator would use the following type of language in the grant application:

> Any necessary IRB approvals will be secured prior to engaging in any research involving human subjects. If funded, the project will require IRB approval for (specify purpose here – such as: questionnaires that will be used to evaluate the efficacy of the grant activities). It is anticipated that IRB approval would be secured no later than June 1, 20xx.

When a grant is funded, the Director of Research and Sponsored Programs (or his/her designee) will notify the IRB Director in writing that a grant involving human subjects research has been awarded. The Director of Research and Sponsored Programs (or his/her designee) will notify Accounting Services of funded programs requiring IRB approval. Accounting Services will be responsible for ensuring that no research related funds are released after the anticipated start date for human subjects research activities unless IRB approval has been secured. To assist in monitoring these cases, a copy of the IRB approval letter will be forwarded to the Director of Research and Sponsored Programs and the Accounting Services office when the applicant has secured IRB permission to conduct research activities.

PART III: Informed Consent

3.1 Purpose of the Consent Document

Informed consent is a process, not just a form. Information must be presented to enable people to voluntarily decide whether or not to participate as research subjects. It ensures respect for people by providing the opportunity for thoughtful consent to ensure that participation is voluntary. The procedures used to obtain informed consent should be designed to educate the subject population in terms that they can understand to ensure that research participants understand the consent they have provided. As a result, the IRB will seek to ensure that the following general requirements of informed consent are satisfied in all studies:

- Informed consent must be prospectively obtained from the participants or their legally authorized representatives;
- Information must be conveyed in understandable language;
- Subjects must be given sufficient opportunity to consider whether they want to participate;
- Consent must be given without coercion or undue influence; and
- Subjects must not be made to give up legal rights or be given the impression that they are being asked to do so.

3.2 Elements of Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

All informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension (45 CFR 46.116(5)). If the project contains no more than minimal risk and the consent form is very brief in length (less than 3 pages), UTC may consider this requirement fulfilled by the entirety of the form itself, and not require a duplicative summary at the beginning of the form.

3.2.1 Basic Required Elements of Consent

Federal regulations on informed consent require the following elements (see Title 45, Code of Federal Regulations, Part 46.116.)

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

2. a description of any reasonably foreseeable risks or discomforts to the subject;

3. a description of any benefits to the subject or to others which may reasonably be expected from the research;

4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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

7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

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

9. one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

    ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

UTC also requires that the following items be included on all consent forms:

1. An explanation of whom to contact with questions about the research, including investigator name and contact information, UTC IRB contact information, and a local contact if applicable.
2. A statement that the research project has been approved by the UTC IRB.

3.2.2 Additional Elements of Informed Consent

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

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Alternate elements of consent must be included when using broad consent, as documented in CFR Part 46.116.(d). However, UTC is not permitting the use of broad consent as defined under Exempt categories 7 and 8 (CFR Part 46.104(d)(7).

3.3 Exceptions to Required Elements of Consent

3.3.1 Social Security Exception

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above (in Sections 3.2.1 and 3.2.2), or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other 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, and

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

3.3.2 Other Exceptions

An IRB also may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the subjects;

2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out with using such information or biospecimens in an identifiable format;

4. the research could not practicably be carried out without the waiver or alteration; and

5. whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

3.4 Documentation of Informed Consent

Except as provided in Section 3.5 below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

1. A written informed consent document that embodies the elements of informed consent outlined previously in this policy (see Section 3.2). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written informed consent document stating that the elements of informed consent required by this policy have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining

consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

3.5 Exceptions/Waivers for Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if 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.

The IRB will usually waive the requirement of signed consent in the following situations:

1. when the identities of subjects will be completely anonymous if the consent form is not signed, and there is minimal risk involved in the study;

2. when obtaining a signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study;

3. when there is a possible legal, social, or economic risk to the subject entailed in signing the consent form, e.g., for HIV antibody-positive individuals who might be identified as such by signing the consent form.

4. retrospective chart review or use of pathological specimens where the patients need not be contacted as part of the study, and appropriate precautions to protect the confidentiality of the data are described;

5. use of extra blood which is taken at the time of a venipuncture being done for clinical reasons; or

6. use of leftover biological material taken from another study for which consent was obtained.

If an investigator does request a waiver of signed consent, then the application should provide a written justification for doing so and cite one of the above categories.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB is likely to require the use of such a written statement, in the form of an information sheet, which includes most or all of the same elements as a consent form, but does not require the signature of the subject.

3.6 General Information to be Considered when Designing Consent Forms

Consent forms should be simple and straightforward so that all subjects will have an easily understood form that outlines the proposed research. As such, investigators should consider the following elements when constructing consent forms:

Reading level: For most studies, consent forms should be written at an eighth-grade reading level.

Lay Language: Use clear, simple wording in informed consent documents. It is rarely appropriate to copy and paste text about the research from a grant proposal or IRB application into an informed consent document. Proposals and IRB applications are written for an audience of doctoral-level reviewers rather than research participants. Unless the participants are themselves medical professionals, scientific or technical terms should either be replaced with or defined in lay language. Active voice should be used to ensure that study participants understand how the various parts of the research will be conducted and by whom.

Active voice wording: "A trained research assistant will ask you questions about your medical history."

Passive voice wording: "Your medical history will be obtained."

Legal terms: Legalistic-sounding language should not be used. These phrases interfere with a subject's comprehension of the consent form and lend the appearance of a legal document to the consent form. (Examples include: "You hereby agree," "You certify that," "You, the undersigned, do acknowledge that," "You understand that," "You realize that," "You have been told that," or "It has been explained to you that."

Proofreading: The entire form should be carefully proofread for correct spelling and grammar before it is submitted for IRB review.

When constructing the consent form, the investigator should review sample consent forms and templates available on the UTC IRB website.

All approved Informed Consent Forms will be finalized in DASH Research when the study is approved. The finalized documents will have a stamp indicating IRB approval date and expiration date. These finalized documents should be used in

PART IV: Adverse Events Report

All investigators conducting research on human subjects must report two types of incidents: if there are 1) any injuries or adverse events associated with the study procedures and/or problems involving the conduct of individuals associated with the study which occur during the course of their research project or 2) any possible breach of human subject protections that an investigator becomes aware of associated with research activities at UTC conducted by other investigators.

As the standard approval letter for the IRB applications states, "All problems involving risks and adverse events must be reported to the IRB immediately." Specifically, the following must be reported, in writing:

- All serious adverse events associated with the study procedures, and/or
- Any incidents or problems involving the conduct of the study or participation by research subjects, including problems with the recruitment and/or consent process.

The information below is provided to clarify IRB policy regarding reporting of adverse events as well as problems involving the conduct of the study.

4.1 Adverse Events that Require a Report

All serious adverse events associated with the study procedures must be reported. All deaths, whether or not they are directly related to study procedures, must be reported. However, common sense must play a large role in deciding what to report; not every bruise or rash needs to be reported. If there is a question, investigators are encouraged to err on the side of "over-reporting."

In general, any serious or recurring problem, any unanticipated side effect, any adverse event reported to a study sponsor and/or to the FDA, any adverse event requiring treatment, or any side effect about which a subject is concerned, should be reported to the IRB Director.

Any problems involving the conduct of the study or patient participation, including problems with the recruitment and/or consent processes also require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.

Any deviations from the approved protocol should be reported in writing. Examples of a more serious nature include incidents of a person being enrolled in a study before signed consent has been obtained, an investigational drug being given prior to signed consent, or a subject being given a higher or lower dose of the drug than stated in the approved protocol.

4.2 Definition of an Adequate Adverse Event Report

Adverse event reports submitted to study sponsors and/or to the FDA may not be sufficient in that they rarely include an assessment of whether changes in the protocol or consent form should be made as a result of the adverse event.

If a study sponsor sends updated drug or device brochures, safety reports or other summaries of adverse effects please forward to the IRB Director. The Principal Investigator should include an appropriate analysis and assessment.

4.3 Special Requirements for Research Involving the Transfer of Genes

In accordance with Appendix M-I-C-4 of the NIH Guidelines, investigators who have received authorization from the FDA to initiate a human gene transfer protocol must immediately report in writing any serious adverse event (SAE) to the IRB, the Institutional Biosafety Committee (IBC), and NIH Office of Biotechnology Activities (OBA) (formerly the Office of Recombinant DNA Activities), and Office for Human Research Protections (OHRP), if applicable.

4.4 The Effect of Reporting an Adverse Event

A report is not an admission of any liability. However, for adverse events, the investigator should make an initial determination as to whether any changes are needed in the discussion of the risks and/or benefits in the consent form. In response to incidents, the investigator may need to re-evaluate the recruitment or consent process and modify existing procedures appropriately.

4.5 The Review Process for Adverse Events and / or Incident Reports

The full IRB Committee will review all adverse event reports and/or incident reports in order to re-evaluate the risks/benefits of the study and/or the appropriateness of the recruitment/consent process to determine if any changes should be made in the protocol or consent form. If the investigator has already modified the protocol or consent form in response to these events, the appropriateness of these changes is also reviewed.

The IRB is responsible for continuing review of all human subject research. This is done through the annual renewal process as required. Thus, all reported adverse events should also be included when a renewal application is submitted for the study, so that the IRB may consider renewal of the protocol in light of such information.

Serious adverse events or incident reports are forwarded to the Provost and Signatory of the IRB who must be informed in case of inquiries, institutional liability, publicity, or to apply for University compensation policies. If the FDA or DHHS is involved, and if the problem is of sufficient magnitude, the appropriate agency officials will be informed. The IRB Director will be responsible for notification in all of these instances.

4.6 The Effect of Failing to Report Adverse Events

Failure to report is a breach of the conditions under which IRB approval is given and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of the right to publish.

4.7 Incident Reports Related to Other Research Activities

The IRB Director will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, students, or faculty. If, for instance, a research project is being conducted without IRB approval, or an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective subjects to participate in a study, the IRB has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to fulfill its obligation to protect human subjects in research, the institution depends upon concerned individuals, including investigators, to inform the IRB Director of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone or in writing to the Provost and other appropriate administrative officials by the IRB Director. An inquiry is made to the investigator conducting the research activity, maintaining requested anonymity of the individual submitting the report whenever possible. Depending upon the outcome of the initial inquiry, information about the incident may be forwarded to the Institutional Official, the Provost, or the Chancellor for appropriate resolution.

PART V: The Health Insurance Portability and Accountability Act (HIPAA)

Federal guidelines establish the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes [45 CFR §§ 164.501, 164.508(f), 164.512(i)]. The Privacy Rule outlined in HIPAA defines the means by which individuals/human research subjects are informed of how medical information about them will be used or disclosed, and their rights with regard to gaining access to information about them when such information is held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.

A researcher is considered to be a covered entity if he or she provides health care services to an individual and transmits that health information electronically to a health care clearinghouse, health plan, or a health care provider as defined in the Transparency Rule (see 45 CFR 160.102 and 160.103).

In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances.

All researchers seeking to conduct projects involving HIPAA covered entities should complete a Form H and submit it with the relevant IRB protocol within DASH Research IRB.

5.1 Disclosure with Authorization by the Research Subject

The Privacy Rule permits researchers to use and disclose PHI for research when participants authorize the use or disclosure of information about themselves. Typically, a research participant's authorization will be sought for clinical trials and some research involving records. In these instances, specific elements must be included in the informed consent form.

5.1.1 Informed Consent under HIPAA

Certain elements and language are required to ensure HIPAA compliance with respect to informed consent and PHI. Refer to the HIPAA Confidentiality Elements Template in Appendix D for the required information. In addition, the HIPAA Authorization Language Template (see Appendix E) must be inserted into the confidentiality section of the informed consent form exactly as written in the Appendix.

A valid authorization for the release of PHI for research also must contain the following required elements in the informed consent form:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner;

2. The name of the covered entity or person(s) authorized to make the requested use or disclosure;

3. The name or other specific identification of the person(s) or entities, which may include the covered entity itself, to whom the covered entity may make the request for use or disclosure;

4. An expiration date and a signature and date;

5. The authorization must be written in plain language;

6. If the authorization is executed by a legal representative authorized to act for the individual, a description of his/her authority to act for the individual must be specified as well as the relationship to the individual;

7. A statement that the individual acknowledges that he/she has the right to revoke the authorization except to the extent that information has already been disclosed under the authorization;

8. A statement that the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the federal privacy law;

9. A description of the purpose(s) of the requested use or disclosure;

10. A statement that the individual may inspect or copy the protected health information to be used or disclosed; and

11. A statement that the individual may refuse to sign the authorization.

Consent forms for actual or potential subjects in a research study must be retained for at least six years from the date permission is granted.

5.2 Research Use: Disclosure Without Authorization by the Research Subject

There are four circumstances that allow HIPAA covered entities to use and disclose PHI for research purposes without authorization by research subjects. These are:

1. Waiver of authorization

2. Review of PHI preparatory to research

3. Research involving a decedent's information

4. Use involving limited data sets

All of these situations require IRB approval.

5.2.1 Application Process for Disclosure of PHI without Authorization by Research Subjects

All applications for disclosure of PHI without authorization by research subjects will require a full board hearing. At such time the IRB will consider the type of PHI which is being considered for waiver and whether the investigators have met the criteria for waiver outlined in the following sections. Normal procedures for full board hearings will be used in hearing waiver applications (see Section 2.3.3). Investigators should submit applications to the Office of Research Integrity via DASH Research IRB. Application forms and DASH Research IRB User Guides can be found at the IRB Website (http://www.utc.edu/irb).

The IRB full-board meets on an ad hoc basis; therefore, investigators should consult the Office of Research Integrity to ensure that they are scheduled for review. Every attempt will be made to schedule a meeting to hear these applications within 3-5 weeks from the time the application is received by the Office of Research Integrity (provided there are no modifications or clarifications needed to the application). The Office of Research Integrity will notify the applicant in writing of all decisions. The IRB approval letter will include the following elements:

1. Identification of the IRB and the date on which the waiver of authorization was approved;
2. A statement that the IRB has determined that the waiver satisfies the pertinent criteria;
3. Provide a brief description of the PHI for which use or access has been determined to be necessary by the IRB; and
4. Note that the request was approved based on a hearing by the full board.

5.2.1.a Securing a Waiver of Authorization

A waiver of authorization may be sought for three specific research uses of PHI:

1. To identify potential research subjects through review of their PHI;
2. To contact potential subjects in order to determine their interest in research participation; and
3. To receive or collect PHI during the conduct of research studies.

A covered entity is permitted to disclose PHI for research purposes without written authorization from the research subject if approval is obtained from the IRB. A covered entity also may use or disclose PHI without individuals' authorizations for the creation of a research database, provided they have documentation that an IRB has determined that the specified waiver criteria were satisfied.

5.2.1.b Criteria to Determine if a Waiver is Authorized

The investigator must provide information about the research study that enables the IRB to determine that three requirements are satisfied:

1. There must be no more than minimal risk to the privacy of individual subjects based on the presence of the following elements:

    i. An adequate plan to protect the identifiers from improper use and disclosure;

    ii. 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 identifiers or such retention is otherwise required by law);

    iii. An adequate written assurance that the PHI will not be reused or disclosed to any other person or entity (except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure is permitted without authorization).

2. It must not be practicable to conduct the research without the waiver or alteration of the authorization requirement; and

3. It must not be practicable to conduct the research without access to and use of the PHI.

5.2.1.c Documentation Required to Secure a Waiver

An investigator may use or disclose PHI for research purposes pursuant to a waiver of authorization by the IRB with documentation of all of the following:

1. The use or disclosure of PHI involves no more than minimal risk to the individuals;

2. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

3. The research could not practicably be conducted without the alteration or waiver;

4. The research could not practicably be conducted without access to and use of the PHI;

5. The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

6. There is an adequate plan to protect the identifiers from improper use and disclosure;

7. There is 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

8. There are 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 project, or for other research for which the use or disclosure of PHI would be permitted by this subpart.

Investigators seeking a waiver of authorization for PHI disclosure without consent of subjects must complete a Form G and submit it to the Office of Research Integrity with the related IRB protocol submission via DASH Research IRB. The Office of Research Integrity will schedule a full board review.

5.2.2 Reviews Preparatory to Research

Investigators may review PHI without authorization to prepare a research protocol (i.e., limited to designing a study and/or determining the feasibility of completing a study). Neither recruitment nor patient contact is considered a preparatory activity. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

1. The investigator shall not remove any protected health information from the covered entity;

2. The use/disclosure of PHI is sought solely for the purpose of preparing a research protocol; and

3. The PHI for which use or access is sought is necessary for research purposes.

In addition, reviews preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference.

Investigators seeking to use PHI in preparation for research must complete a Form I and submit it to the Office of Research Integrity via DASH Research IRB, who will schedule a full board review. Investigators must certify that they have complied with the provisions outlined above.

5.2.3 Research on Decedent's Information

An investigator is not normally required to secure IRB approval for research involving deceased individuals unless other living individuals (such as family members) could be affected (i.e., genetic markers of certain diseases). If the research has no impact upon other living individuals, the investigator may use PHI of deceased individuals without authorization from the decedent's estate. If the research has an impact upon other living individuals, IRB review is necessary. Investigators who are not sure about this determination should err on the side of caution and submit an application for IRB approval.

Qualifications under this provision require that the researcher provide the covered entity:

1. Assurance that the use or disclosure is being sought solely for research on the PHI of decedents;

2. Documentation, at the request of the covered entity, of the death of such individuals; and

3. Assurance that the PHI is necessary for research purposes.

Investigators may use PHI in research on decedent's information if the investigator certifies they have met the provisions outlined above. Investigators must submit a Form J and submit it to the Office of Research Integrity via DASH Research IRB who will schedule a full board review.

5.2.4 Research Involving the Use of Limited Data Sets

Regulations permit covered entities to use or disclose PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

1. Names
2. Postal address information, other than town or city, state and zip code
3. Telephone numbers
4. Fax numbers
5. Email addresses
6. Social security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers
12. Device identifiers and serial numbers
13. Web universal resources locators (URLs)
14. Internet protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images

A limited data set may however, include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

Investigators may use a limited data set for research without subject authorization if they have completed a Limited Data Use Agreement with the entity releasing the data. Investigators in this situation should complete a Form H and provide it and the Limited Data Use Agreement with the IRB protocol submission to the Office of Research Integrity (Normally, the entity releasing the data should provide the Limited Data Use Agreement; however, if the entity does not have such a form the investigator should contact the Office of Research Integrity for examples of acceptable forms).

5.3 Use of De-identified Data in Clinical Research

Under HIPAA, PHI can be released freely if it does not contain "individually identifiable information" as defined in the section above. PHI is not individually identified if the subject is not identified, directly or indirectly, and if the subject has no reasonable basis to believe that the information can be used to identify them. Research using de-identified data does not meet the federal definition of research and is not subject to the Common Rule. For these conditions to be met, none of the subject identifiers listed in the previous section can be reviewed or recorded by the research team. In order to de-identify PHI, HIPAA covered entities must utilize one of the two following procedures.

5.3.1 Procedures to De-Identify Datasets

HIPAA regulations allow HIPAA covered entities to use two procedures to de-identify data sets so that they may use or disclose PHI for research purposes without securing waivers. These procedures are:

5.3.1.a Use of a Statistician

HIPAA covered entities may obtain the services of a person with appropriate experience and knowledge who applies generally accepted statistical and scientific principles and methods to determine that the information is not individually identifiable; there is a very small risk that the information could be used by itself or in combination with other available information by the anticipated recipient(s) to identify the subject with the information; and who will document the methods and results in making such a determination.

5.3.1.b Removal of Identifiers

To comply with the HIPAA Security Rule, HIPAA covered entities must ensure that all identifiers listed above have been removed and certify that they have no actual knowledge that the information remaining could be used alone or in combination with other information to identify individual patients.

5.4 Investigators' Responsibilities Maintaining Databases

In order to be in possession of a research database containing PHI, a researcher must have patients' authorization, a waiver of authorization from the IRB, or use a limited data set covered by a Data Use

Agreement. If an investigator maintains a database containing PHI, then the investigator has an obligation to ensure that the use and disclosure of PHI are in compliance with policies, regulations, and any agreements required by the data provider. The investigator is responsible for:

1. Maintaining applicable security for the database, including physical security and access controls set forth in a Data Use Agreement, Data Sharing Agreement, or equivalent;

2. Controlling and managing the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and

3. Ensuring that any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

5.5 Studies and Databases Initiated Prior to HIPAA

Databases created prior to April 14, 2003, are grandfathered in and do not have to meet the Privacy Act policies. Studies involving subjects that have enrolled prior to April 14, 2003, will not be required to re-consent. Investigators may continue to collect and use data gathered from these subjects and no new documentation is required.

5.6 Research Participants' Right of Access to Research Records

With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about them that is maintained in a "designated record set." A designated record set is a group of records that a covered entity uses to make decisions about individuals and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. Research records or results maintained in a designated record set are accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions, however, applies to PHI created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access PHI will be reinstated at the conclusion of the clinical trial.

Appendix A: Historical Background

For many years, state and federal laws were silent on the issue of human research and experimentation. The situation changed, however, in 1971 with the first of a series of federal regulations. The then US Department of Health, Education and Welfare (DHEW) issued The Institutional Guide to DHEW Policy on Protection of Human Subjects. These guidelines set the initial review criteria into motion. Three years later, on July 12, 1974, Public Law 93-348 (known as the "National Research Act of 1974") was signed into law, creating the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, and set the definitive standards of the Institutional Review Board. Section 212 of the law specified, in part, that:

> "The Secretary of DHEW shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application assurances satisfactory to the Secretary that it has established a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects...in order to protect the rights of the human subjects of such research."

The Belmont Report was published on April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report was an outgrowth of intensive discussions held in February 1976 at the Smithsonian Institution's Belmont Conference Center that were supplemented by the monthly deliberations of the Commission that were held over a period of three years. The Belmont Report is a statement of basic ethical principles and guidelines meant to assist individuals in resolving ethical problems that surround the conduct of research with human subjects.

Two years later, on January 27, 1981, the Food and Drug Administration (FDA) and the National Institutes of Health set the regulatory standards in place for the Protection of Human Subjects and for the Operating Standards of the Institutional Review Boards.

On March 8, 1983, the US Department of Health and Human Services (DHHS), in response to the Belmont Report and the FDA's standards, extensively revised its 1974 basic policy and added new regulations governing additional protection for special classes of human subjects -- fetuses, pregnant women, in vitro fertilization, prisoners, children, mental and physical disabled or institutionalized individuals, and the elderly.

In April 1989, the White House Office of Science and Technology ordered all government agencies to adopt the DHHS policy as their own, with the Office for Human Research Protections (OHRP) of the National Institutes of Health as the coordinating agency. On June 18, 1991, OHRP issued its revised policies for the Protection of Human Subjects and two months later, on August 19, 1991, the regulations became effective, with OHRP becoming the coordinating agency for 19 US government agencies to ensure that institutions comply with the federal regulations, which protect human subjects in research. The regulations are known as the Model Federal Policy of 1991, the “Common Rule”, or simply by its legal citation, 45 CFR 46.

On January 18, 2017, DHHS in partnership with 15 other Federal Departments and Agencies revised the Federal Policy for the Protection of Human Subjects in an effort to modernize, simplify, and enhance the current system of oversight (Revised Common Rule). This rule was originally set to be effective on January 19, 2018. A subsequent rule delayed implementation of the Final Rule until January 21, 2019.

Appendix B: Exempt Category Definitions

According to the Department of Health and Human Services regulation 45 CFR 46. 104, there are eight categories of human subject research that are exempt under federal jurisdiction. Each category of exempt research is listed below.

Exempt Category 1:

The research is conducted in established or commonly accepted educational settings, involving normal education practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt Category 2:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording if *at least one* of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review.*

Exempt Category 3:

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review.*

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the

investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exempt Category 4:

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) *Note: This exemption applies only to research conducted by personnel at HIPAA covered entities. The University of Tennessee System is a hybrid entity. UT Health Science Center campuses and clinics have been designated as covered components within the UT system; other campuses and clinics have not. Thus, this exemption is not available to UTC researchers.* The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined as 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

Exempt Category 5:

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine the public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may

determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Exempt Category 6:

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.

The University of Tennessee at Chattanooga will not be implementing broad consent, so exempt category 7 and 8, although listed below, will not be applicable to research conducted by this institution.

Exempt Category 7 (not applicable at UTC):

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination required *by* §__.111(a)(8).

Exempt Category 8 (not applicable at UTC):

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(b), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §.111(a)(7) and makes the determination the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

The IRB Chair or his/her designee must review any exempt designation proposal before the proposed research may proceed and the investigator must receive a letter from the Office of Research Integrity confirming this decision. There is no such thing as an emergency exemption and no university official other than the IRB Chair or his/her designee may designate research as exempt.

Appendix C: Expedited Category Definitions

Definition of Expedited Categories

Federal regulations and institutional policy allow for expedited review of certain types of research that have been determined to place a human subject at *minimal risk* in a research setting (45 CFR 46.110 and 21 CFR 56.110).

Investigators may apply to the IRB for expedited review if their research falls into one of the nine categories discussed in the following section; although the activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the proposed research involves minimal risk to human subjects. Both the Applicability and the Research Categories sections of the regulations need to be considered in order to qualify for expedited review; however*, if subjects will be randomized to treatment and control groups, then the study does not qualify for expedited review.*

Applicability

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

2. 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 not greater than minimal.

3. The expedited review procedure may not be used for classified research involving human subjects.

4. 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.

5. Categories one (1) through five (5) pertain to both initial and continuing IRB review.

Research Categories

1. A very limited number of studies of approved drugs and devices: Clinical studies of drugs and medical devices 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 (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Note: The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review. Few studies fit this category.

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

    a. From healthy, non-pregnant 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 children, 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.

    Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted" 45 CFR 46.402(a).

3. Noninvasive specimen collection: Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring 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); (c) 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. Noninvasive clinical procedures: 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. Use of data or specimens collected for non-research purposes: 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 46.104. This listing refers only to research that is not exempt.)

   (Note: (a) This category refers to materials collected for "non-research purposes," but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with code numbers and other protections for confidentially, he or she may apply for expedited review for the analysis; (b) This type of research is exempt from review only if the data collected has no link whatsoever to identifiers (not even a code number).

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

7. Low risk behavioral research: 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 46.104. This listing refers only to research that is not exempt.)

   (Note: Only very specific types of behavioral research are exempt from review. Again, there usually must be no link whatsoever to identifiers [not even a code number.]

8. Renewal of inactive research protocols or protocols that are essentially complete: 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. Renewal of other minimal risk research protocols: 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.

The IRB Committee must approve any expedited proposal before the proposed research may proceed and the investigator must receive a letter from the Office of Research Integrity confirming this decision. There is no such thing as an emergency exemption, and no university official other than the IRB Committee may grant approval.

Appendix D: HIPAA Confidentiality Elements Template: For the Confidentiality Section of the Consent Form in Research involving HIPAA Rules and Regulations

Ensure the following information is included in your informed consent form within the Confidentiality section:

CONFIDENTIALITY:
1. Provide a statement explaining how individual identifiers will be used in maintaining the research records (i.e., research record labeled with subject's name or research records labeled with a code number. A master key that links the name and code number will be maintained in a separate and secure location).

2. Insert HIPAA authorization portion in confidentiality section. (refer to HIPAA authorization language template, Appendix E).

3. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure. *(Example: To further help protect your privacy, the investigators have obtained a confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this federal Certificate, the investigators cannot be forced (i.e., court order) to disclose information that may identify you in any federal, state or local court. However, disclosure is necessary upon the request of the DHHS (i.e., for audit or program evaluation).*

4. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's medical record (as contrasted with research record), then it should be specified.

5. Specify that the individual subjects will not be identified in any presentations or publications based on the results of the research study.

Appendix E: HIPAA Authorization Language Template: HIPAA Portion of the Confidentiality Section of the Consent Form

PLEASE NOTE:

The authorization language provided below should be inserted at the appropriate location in the confidentiality section of the consent form. The language in the template should be directly followed.

Study records that identify you will be kept confidential as required by law. Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "PHI") which provides safeguards for privacy, security and authorized access. PHI collected in this study may include **[INSERT SPECIFIC CRITERIA AS IT RELATES TO YOUR PROTOCOL- Examples to include:** your medical history, results of physicals exams, lab tests, x-ray exams, other diagnostics and treatment procedures, as well as basic demographic information.] In addition to the investigator(s) listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study. A representative of the University of Tennessee at Chattanooga Institutional Review Board may review your PHI for the purpose of monitoring the appropriate conduct of this research study. **[Remove the following sentence if not applicable to your protocol** - Reviewers may also include representatives from the Food and Drug Administration for the purpose of monitoring the accuracy of the research data, legal counsel, and your medical insurance carrier.] The University of Tennessee at Chattanooga Institutional Review Board may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. **[Remove the following two sentences if not applicable to your protocol** - PHI may also be shared with the sponsor of this study, **(INSERT SPONSOR)**, for the purpose of monitoring the accuracy and completeness of the research data and performing required scientific analyses of the research data. The investigators involved in the conduct of this research may receive funding for the sponsor to perform the research procedures and to provide the sponsor with identifiable research information related to your participation]. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which your PHI has been approved by the Institutional Review Board. Please be aware that once PHI is disclosed, there is the possibility that your personal health information may no longer be protected by applicable privacy laws and regulations.

The study results will be retained in your research record for a minimum of six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results. Any research information obtained in your medical record will be kept indefinitely.

This authorization does not expire. At any time, you may cancel this authorization in writing by contacting the principal investigator listed on the first page of the consent form. If you decline to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. However, information gathered before the cancellation date may be used if necessary in completing the research study or any follow-up for this study. [**Remove the following sentence if the protocol is a non-clinical study** - You are permitted to obtain access to your PHI collected or used in this study. Such access will be granted at the end of the study].