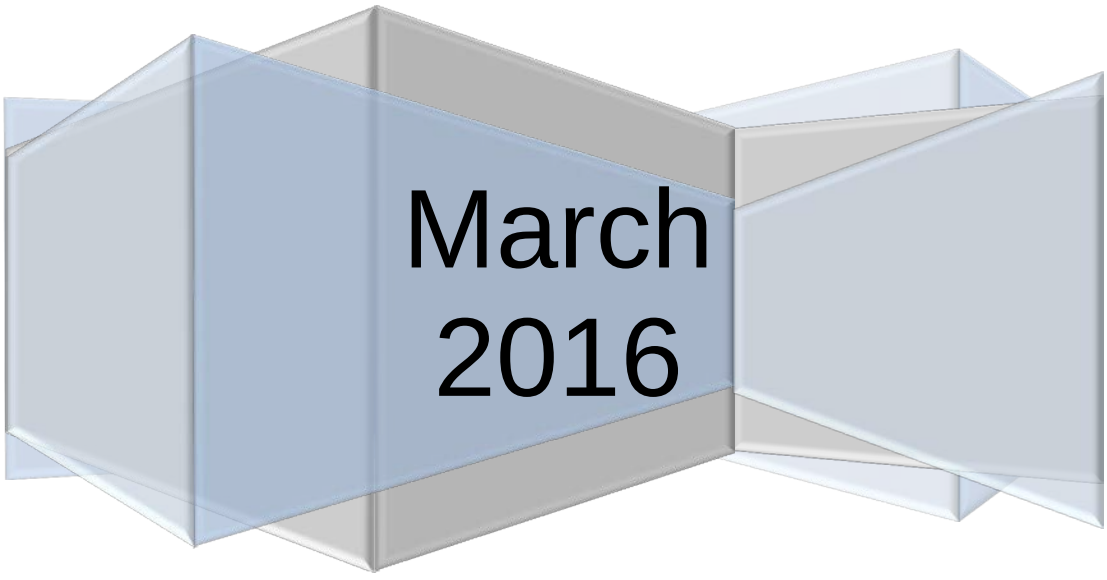
Department of
Mental Health &
Substance Abuse Services

TDMHSAS

Institutional Review Board (IRB) Policy and Procedures



Updated July 20, 2016

Table of Contents

I. Policy on Departmental Oversight of Federalwide Assurance (FWA)

Policy:

It is the policy of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) to apply for and uphold the Federalwide Assurance (FWA) filed with the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP).

The IRB has not "checked the box" on its FWA application form so the FWA only has to be applied to federally-funded research. Thus, OHRP oversight applies only to federally- funded research, not all research conducted by or for TDMHSAS.

A. Basis of Federalwide Assurance (FWA)

1. The TDMHSAS IRB will maintain a valid Federalwide Assurance (FWA) through DHHS, OHRP.

    a. Hard copy and an electronic version of TDMHSAS' Federalwide Assurance (FWA) will be maintained in the office of the IRB Administrator, and will be available to TDMHSAS IRB members as well as prospective researchers upon request. TDMHSAS' FWA is based on the following principles:

        1) The charge of the TDMHSAS IRB is to protect the welfare and rights of human participants in research and other research activities involving service recipients/participants in TDMHSAS facilities (i.e., the Regional Mental Health Institutes [RMHIs]) and/or programs managed directly by TDMHSAS Central Office staff. Departmental authority is delegated by the Commissioner to the Chief Medical Director for TDMHSAS who serves as IRB Chairperson.

        2) The TDMHSAS IRB also has responsibility for research activities where programs are funded by TDMHSAS, i.e., grant-funded programs, even though the participants are not in facilities or managed by Central office staff

            a) Research encompasses activities designed to develop or contribute to scientific generalized knowledge.

b) Research activities may include studies involving human participants, records research, specimen research, and research specified in grant proposals.

c) Research applies to all studies undertaken by or for TDMHSAS and includes any request to use service recipients, their records, or their specimens for research purposes.

The IRB will uphold the ethical principles delineated in The Belmont Report. Those principles include:

1) **Respect for Persons**. This principle holds that research participants should be treated with dignity as self-directed agents and that special consideration should be addressed when participants may have diminished autonomy.

2) **Beneficence**. This principle emphasizes the dictum of "do no harm" so that expected benefits are maximized and possible risks of harm are minimized.

3) **Justice**. This principle focuses on the fairness in which research benefits and burdens are distributed.

b. The TDMHSAS IRB will apply regulations 45 Code of Federal Regulations (CFR) 46, Subpart A, better known as the Common Rule, in its work. Regulations 45 CFR Part 46 contain subparts B, C, D & E, as well. The subparts deal with the following:

1) Subpart A – Basic DHHS Policy for Protection of Human Research Subjects (also known as the "Common Rule")

2) Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

3) Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

4) Subpart D– Additional Protections for Children Involved as Subjects in Research

5) Subpart E – Registration of Institutional Review Boards

The IRB further will apply additional regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when appropriate, in reviewing research involving human participants. Specifically, the IRB will adhere to 45 CFR Parts 160 and 164. The HIPAA Privacy Rule, which requires appropriate safeguards in the protection of the privacy of protected health information (PHI) and sets conditions and limits on uses and disclosures that may be made of such information without service recipient/participant

authorization, is located at 45 CFR Part 160 and Subparts A and E of Part 164. Moreover, the Rule gives service recipients/participants control over their health information. This Policy does not override any law or rule that provides greater protection of PHI, including Tennessee Code Annotated (TCA) Title 33 and 42 CFR Part 2 of the Confidentiality of Alcohol and Drug Abuse Patient Records. Title 33 is the section of the TCA that pertains to codes and laws that govern mental health care here in the state. There are special privacy protections for patient records of drug and alcohol users in 42 CFR Part 2. The regulations outline the limited circumstances under which a patient's treatment may be disclosed with or without his/her consent.

At the time of this writing, DHHS has plans to modify the existing rule (i.e., 42 CFR Part 2). The rule currently prohibits the sharing of substance use treatment records with other providers without the consent of the patient. As proposed, modifications would allow patients seeking substance use treatment to participate in new integrated healthcare models that are built upon information sharing, coordinated care, and electronic health records. The modification will still protect patients against damaging and inappropriate disclosures of their substance use treatment record. The Board will operate in alignment with the new rule when it is implemented.

B. Structure of the Institutional Review Board.

1. IRB membership is approved by the TDMHSAS Commissioner and must consist of at least five (5) members.

2. Every reasonable effort will be made to maintain nine (9) members on the IRB.

3. The Chief Medical Director is the appointed IRB Chairperson.

4. In accordance with Federal regulations, the TDMHSAS IRB contains at least one member that is a nonscientist and at least one member that is not a departmental staff person.

5. Per Board resolution, at least one member should be clinical staff from one of the department's RMHIs or central office staff from the Division of Hospital Services.

6. At least one community member who is representative of the behavioral health field will be recommended for membership.

7. IRB members are approved by the Commissioner, and have complete review, discussion, and voting rights. (An IRB member may be appointed by the Chairperson to function as the Co-Chairperson. This individual will perform designated roles and responsibilities of the Chairperson in his or her absence.)

8. Other individuals including student interns may be invited to participate in IRB meetings. They can provide information regarding specific proposals, review submitted material, answer questions from the membership, and engage in discussion. However, these individuals will not have voting privileges.

C. IRB Responsibilities of Oversight for Its Federalwide Assurance (FWA)

1. The TDMHSAS IRB operates under FWA # 00018874. The IRB operates under # IORG0003911.

2. IRB approval is required prior to the engagement/enrollment of service recipients/participants in research related to programs managed or funded by TDMHSAS. (Research is defined in Section I.A.2.a.1)a)-c) of this document.)

3. Through the review process, the IRB has the authority to approve, approve with condition(s), disapprove, close-out, hold, suspend, or terminate all research activities that fall within its purview.

4. Meetings are typically scheduled monthly. Efforts will be made to designate a standard date and time for each monthly meeting, e.g., every 3rd Friday from 9:30 a.m. to 11:00 a.m. central time. However, meeting dates/times may require adjustment to ensure the presence of a quorum. Meetings may be canceled in the event there are neither proposals to review nor pertinent business to discuss. The TDMHSAS-IRB membership can attend meetings in person, by phone, and/or through other technological means.

5. Studies involving more than minimal risk require full review and must be handled during a convened meeting.

6. A quorum, i.e., the majority of the total TDMHSAS-IRB membership, is required to vote on proposals for full review. The quorum can be formed face to face and/or via conference line or other technological means. *(Other IRB business not specifically dealing with research proposals/amendments would not require a quorum for approval. However, voting would be required.)*

    a. No TDMHSAS-IRB member with a conflicting interest shall cast a positive or negative vote during review of a research study or amendment(s). These members may provide information or clarification as requested by the membership. Members having such conflicts must cast a recusal vote.

7. Studies involving no more than minimal risk may not require full review and hence might not be handled during a convened meeting. Review of such studies can be expedited, involving as few as a single member designated by the TDMHSAS-IRB Chairperson (or Co-Chairperson in the absence of the Chairperson). (*See Section III.B.5 on expedited review.*) All expedited reviews will be summarized and presented at the next full review meeting or through minutes or summaries distributed to the membership when meetings are canceled.

8. All research reviews must address issues involving vulnerable populations, if indicated. Vulnerability occurs when an individual's ability to protect himself or herself is diminished or absent. Vulnerable populations are more susceptible to both inadvertent and intentional harm and include: children and youth, women of child-bearing potential, pregnant women, fetuses and human in vitro fertilization, prisoners, and cognitively impaired individuals.

   The Common Rule (Title 45, Part 46 of the Code of Federal Regulations) identifies various categories of vulnerable populations. As a result, the IRB and researchers must give special consideration to protecting their welfare and ensuring voluntary research participation and freedom from coercion.

   a. *Children and Youth*. Parents are required to give consent for research participation of their children. One parent can provide consent when the research involves only minimal risk. There are also extenuating circumstances that allow one parent to consent to research for his/her children. Among the circumstances are when the other parent is incarcerated, deceased, does not have legal responsibility/custody, or not reasonably available. Research involving greater than minimal risk typically will require that both parents give consent. Extenuating circumstances can override that requirement, however. The IRB may choose to allow consent from one parent when the research is of direct benefit to the child, despite the fact that the study is greater than minimal risk. Nevertheless, assent must be attained from any child that participates in the research study and is capable of giving assent. In addition, children must be allowed to give dissent, i.e., the opportunity to withdraw from the study. Parents or adults can also choose to dissent.

      In Tennessee, Title 33 gives the same rights to youth 16 years of age or older with respect to inpatient and outpatient mental health treatment, confidential information, medication decisions, and participation in conflict resolution procedures except where provided in Part 3 of Chapter 8 or otherwise expressed in the title. This means that a behavioral health professional or an outpatient facility may provide rehabilitation and treatment without obtaining consent from the parent, legal guardian, or legal custodian if the youth is at least 16 years of age. The law, on the other hand, does not forbid mental health providers from asking parents to give consent if the youth has not reached the age of majority (at least 18 years of age in our state). In

those cases, youth ages 16 or 17 would need to complete assent documents to participate in research and the parent/guardian would sign the "consent to participate in research" document.

b. *Women of Child-bearing Potential*. These women are considered vulnerable because of risks to any unborn children if they become pregnant. Their vulnerability is more often associated with clinical research (Schwenzer, 2008). Nevertheless, researchers are encouraged to involve this population in their research, whenever appropriate. Women of child-bearing potential should be informed regarding any precautions related to their breast feeding or becoming pregnant while a service recipient/participant in the study. Any other concerns for this population should be included in consent forms and/or in other discussions/documents related to research participation.

c. *Pregnant Women and Fetuses*. The vulnerability of the pregnant woman is directly related to the potential for harm to the fetus. Therefore, research participation for pregnant women should be limited to no greater than minimal risk. These limitations apply to breast-feeding women as well.

d. *Prisoners*. This population has been defined as persons involuntarily confined in a penal institution, which includes persons detained pending arraignment, trial, or sentencing, and in the psychiatric hospital. Prisoners can be recruited for research only under certain conditions: when a study has the potential for direct benefit to the prisoner. It requires a lot of work to get research involving this population approved by an IRB but approval is not impossible when appropriately designed and focused.

e. *Persons with Cognitive Impairment*. Persons with cognitive impairment may have cognitive, developmental, or psychiatric disorders; be in an unconscious state or critically ill; or have diminished capacity for reasoning and judgment. They should have the opportunity to be involved in research, but only if they are the sole appropriate, service recipients/participants; the research question is unique to the population; or the research involves no more than minimal risk. In some cases, surrogate consent and assent might be most appropriate.

9. OHRP further recognizes special or at-risk populations such as residents, employees, students, minorities, and terminally ill patients. Regarding vulnerable populations, the IRB should ensure that appropriate safeguards are in place. For vulnerable and/or at-risk populations, the IRB must carefully examine whether the research:

   a. Involves more than minimal risk to the service recipient/participant.

   b. Is likely to benefit the service recipient/participant directly, even if the

risks are considered to be more than minimal.

c. Involves greater than minimal risk with no prospect of direct benefit to individual service recipients/participants, but is likely to yield generalizable knowledge about the service recipient/participant's disorder or condition.

d. Presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the service recipient/participant.

Requests for approval of research that exposes vulnerable or at-risk populations to risks that do not fall in one of the aforementioned categories must be submitted to the DHHS secretary for review and approval.

10. Research reviewed and approved by the IRB may be subject to review and disapproval by the executive leadership of TDMHSAS. However, executive leadership may not approve research previously disapproved by the IRB.

11. All research proposals and/or other associated materials including voting results, meeting minutes, and agenda shall be accessible for inspection and/or copying by authorized representatives or designees of OHRP or other appropriate federal agencies at reasonable times and in a reasonable manner.

    a. This policy applies to approved and non-approved research proposals.

    b. This policy applies to proposal amendments and/or other business topics/discussions related to research activities.

12. The IRB will retain copies of all approved proposals and/or other materials related to disposition for as long as the researcher must maintain records. Proposals not approved will be maintained for a period not to exceed three (3) years. Electronic filing can be utilized for record maintenance.

13. The TDMHSAS IRB may suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with severe unexpected harm to participants. Issues around suspension, e.g., failure to submit continuing review or close out or complaints reported to the TDMHSAS-IRB office, will be brought to the membership for resolution. The IRB Administrator will follow up to ensure Board actions are implemented.

14. The IRB may officially close-out a study when requested by the researcher because participants are no longer being enrolled or followed up and any

analysis, if being conducted or continued, will involve only de-identified data. Requesting close-out further requires that Principal Investigators (PIs) tell the IRB how study data will be securely stored, maintained, and/or destroyed. Close-out may be mentioned in concert with continuing review notification.

II. Procedure for Departmental Oversight of Federalwide Assurance (FWA)

Procedure:

This procedure delineates responsibilities of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) in maintaining the TDMHSAS FWA.

A. IRB Responsibilities

1. IRB members will participate in ***valid*** human subjects' protection training at minimum every three (3) years.

2. Newly appointed TDMHSAS IRB members will obtain ***valid*** human subjects protection training within six (6) months of appointment to the Board.

3. Teachable moments at IRB meetings may be used to provide additional training for membership.

4. The IRB will conduct initial review of research activities involving appropriate studies as delineated in Section I.A.1.a.1a-1)c of this document.

5. The IRB will conduct continuing review of research activities involving appropriate studies as delineated in Section I.A.1.a.1)a-1)c of this document.

6. The IRB will conduct review of amendments to previously approved research as necessary.

7. The IRB will close-out a study when notified by the Principal Investigator (PI) or his or her designee because service recipient/participant enrollment or follow-up has ceased and analyses involve only de-identified data.

8. The IRB may take other actions such as suspending research activities whenever warranted.

B. Administrative Requirements of the IRB

1. In order to maintain an active FWA approved by OHRP, the IRB Administrator will enter or update TDMHSAS information at least every five (5) years, even if no changes have occurred.

2. The IRB Administrator will ensure that all necessary updates, including changes to the membership, are reported to OHRP in a timely manner.

3. The IRB Administrator will maintain and/or disseminate policies and procedures related to this IRB in the conduct of reviews and approvals under the FWA. In addition, the IRB Administrator shall fulfill the following responsibilities:

   a. Manage training opportunities including updates for the IRB membership.

   b. Handle queries regarding the IRB and its operation, including informing applicants of the review process and keeping meeting schedules.

   c. Receive research proposals, including amendments, for review and prepare them for distribution to the IRB membership. Proposals may be submitted electronically and/or in hard-copy format. Every reasonable effort will be made to give membership at least seven (7) days to review a proposal. In no instance should membership be expected to provide review of a research proposal received the day before or day of a scheduled IRB meeting.

   d. Determine if a study or any amendments require full or expedited review, in collaboration with the IRB Chairperson (or Co-Chairperson in the absence of the Chairperson).

   e. Document and maintain records of IRB activities for a period not less than three (3) years, as defined by Federal regulations 45 CFR.

   f. Receive necessary information required for the IRB to officially close-out a study.

   g. Schedule and/or notify the IRB membership of meetings. (Notification can be provided electronically.)

   h. Develop and/or maintain appropriate forms necessary to conduct IRB business.

   i. Prepare and maintain agendas and meeting minutes.

   j. Stamp all approved research documents appropriately.

   k. Inform principal investigators (PIs), researchers, and/or evaluators regarding the status approved proposals within ten (10) working days of the IRB's decision, along with stamped documents. In situations where approval involves conditions, provide conditional information within ten (10) working days of the IRB's decision. Researchers will be given up to

30 days to meet conditional requirements without penalty to the research study/project, unless otherwise indicated. Stamped documents will be provided within ten (10) working days of approval of conditional materials. Proposal status may be provided electronically and/or in hard-copy format. Official notification of approval will be sent in the form of a letter signed by the TDMHSAS-IRB Chairperson, with copies to the TDMHSAS Commissioner and Deputy Commissioner.

l. Notify researchers regarding continuing review, if possible. (NOTE: Researchers are responsible for contacting the IRB Administrator about continuing review, whether or not they received reminder notification from the administrator.

m. Prepare and/or update information for the TDMHSAS-IRB Web page.

n. Participate in training sponsored by OHRP or other reputable groups at minimum every three years and share training information/materials with the membership.

C. Responsibilities of Principal Investigators (PIs)/Persons That Submit Requests to Conduct Research

1. Principal Investigators (PIs) and/or their submitting agent must submit research proposals for initial or continuing within twenty (20 days) of scheduled TDMHSAS-IRB meetings to ensure timely review will occur. (The TDMHSAS IRB will attempt to re- convene a full meeting sooner than the following month when failure to review occurs because a quorum could not be established. If that option cannot be implemented, every effort will be made to ensure review at the next scheduled meeting. The Board will also work with the PI to provide a “30-day grace” period for study expiration under these circumstances.)

2. Proposals received outside the window of scheduled meeting dates should allow at least thirty (30) days for review. This means that review may or may not occur at the next regularly scheduled meeting. In addition, the Board will not necessarily provide a “30-day grace” period for this situation because the submission did not meet the appropriate time requirement. As a result, enrollment into research for continuing review projects may be suspended until review and approval have been provided. Research activities can be re-instituted once continuing review approval has been rendered.

3. PIs should ensure the quality of proposals, including amendments, and other necessary documents that are submitted for review. Spelling and grammatical errors should be minimal. A suggested, formatted proposal is available on the TDMHSAS Web site at

http://tn.gov/assets/entities/behavioral-health/attachments/Suggested_IRB_Proposal_Format.pdf for use by researchers, as well as in the appendices of this manual. The researcher may choose to submit a proposal in his or her preferred format, which is acceptable. However, care should be taken to include all required sections as indicated in the suggested, formatted proposal document. A copy of the suggested, formatted proposal is additionally contained in this manual in the Appendices.

4. PIs and/or their submitting agent must include all materials required for review, as indicated on the TDMHSAS IRB Web page or mentioned in this document. This includes cover letters and the correct reference to this department or the acronym: Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS).

5. PIs must sign and date all proposals and/or amendments submitted for review whether or not he or she is the submitting agent.

6. The Principal Investigator (PI) must demonstrate appropriate knowledge of human participant protections, ethics, Federal regulations, training, and monitoring as it relates to conducting his or her proposed research. Documentation of such knowledge must be submitted in the form of a ***valid*** human subjects' protection training certificate. The training certificate can come from the National Institutes of Health (NIH), the Collaborative Institutional Training Initiative (CITI), or some other reputable training entity, preferably at the time the research proposal is submitted for review, but certainly in advance of receiving notification of proposal approval. Exceptions include when the PI has a ***valid*** training certificate on file with the IRB through a previously reviewed or continuing study. ***Valid*** is defined as within three (3) years from the date on the certificate.

7. In addition to the PI, persons identified in the proposal as key study personnel because they will collect data directly from the service recipients/participants and/or they will have access to the service recipients/participants or data at some point in time during the study must also demonstrate appropriate knowledge of human participant protections, ethics, Federal regulations, training, and monitoring as it relates the proposed research. Documentation of such knowledge must be submitted in the form of a ***valid*** human subjects' protection training certificate. The training certificate can come from the National Institutes of Health (NIH), the Collaborative Institutional Training Initiative (CITI), or some other reputable training entity, preferably at the time the research proposal is submitted for review, but certainly in advance of receiving notification of proposal approval. Exceptions include when the key study personnel have a ***valid*** training certificate on file with the IRB through a previously reviewed or continuing study. ***Valid*** is defined as within three (3) years from the date on the certificate.

8. PIs can submit amendments to currently approved research at any time.

Depending on the amendment request, amendments may be expedited or involved in full review. Amendments involving minor changes that will not increase risk for participants, such as a change in evaluator, will most likely be expedited.

9. Close-out requests should be made when there is no more enrollment or follow-up of participants and any analyses to be completed only involve de-identified data. Close- out requests should further include information about data storage, retention, and usage. PIs must guarantee that data will continue to be securely stored in locked cabinets in locked rooms, retained the appropriate length of time (ten [10] years from the close of the study for adults and ten [10] years after the last minor participant has turned 18 years of age), and used solely for academic or professional purposes, not for personal or financial gain.

10. Close-out requests should document the reason for the request, include a summary of the research findings (or mention when such findings will be available), and describe in detail how study data will be securely and appropriately stored, maintained, and/or destroyed. The following guidelines should be followed for maintenance of study data.

    a. For Adults
    Mental health records must be maintained for ten (10) years after termination of services/discharge.

    b. For Minors
    If the minor receives services as a minor, then the minor's mental health records must be maintained for ten (10) years after the minor reaches the age of majority (18 years of age in Tennessee).

    The aforementioned guidelines were taken from the Department of Mental Health Record Disposition Authority Report dated March 19, 2012. Secure electronic storage/maintenance of data is acceptable if there are appropriate protections.

11. If necessary, close-out requests should include notices to participants regarding close- out of the research.

III. Policy on Activities Subject to IRB Review

Policy:

It is the policy of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) to review research/research activities involving service recipients/participants in

TDMHSAS facilities (i.e., the RMHIs) and/or programs funded by or through TDMHSAS.

D. Review and Approval of Human Subjects Research

1. All human subjects research, and all other activities, which in part include human subjects research, involving service recipients/participants in TDMHSAS facilities (i.e., the RMHIs) and/or programs funded by or through TDMHSAS must be reviewed and approved by the TDMHSAS IRB. ***PROGRAM EVALUATION ACTIVITIES DO NOT NECESSARILY REQUIRE IRB REVIEW***. Program evaluation activities are typically undertaken to examine the effectiveness of a specific service, practice, or program. However, if, from the outset, information from the program evaluation activity is going to be generalized to other programs, it is human subjects' research and should be submitted to the IRB. Such is not the case for most program evaluation activities. Researchers are asked to consult with the IA if they have questions about how to proceed.

2. The IRB must review all human subjects research if one or more of the following apply:

   a. The research involves the use of service recipients, their records, or biological specimens from TDMHSAS' Regional Mental Health Institutes (RMHIs).

   b. The research is sponsored by TDMHSAS.

   c. The research is conducted by or under the direction of any staff, student, or agent of TDMHSAS in connection with his or her departmental responsibilities.

   d. The research is conducted by staff in a state-funded program for which TDMHSAS has monitoring responsibilities.

   e. TDMHSAS receives a direct Federal award to conduct human subjects research or there is an IRB requirement as part of the evaluation activities, even when all activities involving human subjects are carried out by a subcontractor or collaborator.

3. IRB review and approval is also required when data originally collected for non- research purposes will be used in research.

   Sometimes materials (including data) that have been collected for program evaluation purposes, e.g., will later be used to generalize to similar programs. In this case, the IRB can review the proposal as research involving secondary use of existing data. The IRB should discuss whether the

submission will be accepted. The IRB may fail to review the proposal if there are indications that earlier submission was not conducted to avoid the IRB.

4. The TDMHSAS IRB will conduct initial and continuing reviews, as well as review of amendments for currently approved research.

   7) Initial Review (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)

   1) Initial review encompasses the first review of a research proposal/other research activities by the TDMHSAS IRB. The review may be undertaken for any research activity identified in Section III.A.2.

   2) Requests for initial review must conform to and comply with appropriate laws and regulations. For example, the research must conform to policies outlined in 45 CFR, Part 46, Protection of Human Subjects. In addition, the research must comply with current TDMHSAS policies regarding the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. This policy does not override any law or rule that provides greater protection of Protected Health Information (PHI), including Tennessee Code Annotated (TCA) Title 33 and Part 2 of the Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR).

   3) Requests to conduct research requiring initial review must be in writing and include a cover letter addressed to the TDMHSAS-IRB Chairperson.

   4) Proposals must contain a concise, yet thorough, description of the study, including:

      a) Study title;

      b) Study purpose;

      c) Research questions or hypotheses;

      d) Research design including information on the target population;

      e) Research method(s) including instrumentation (commercial or locally developed);

      f) Research ethics[1] including informed consent procedures and forms, as well as how the data will be collected and protected; and

g) Data analysis.

5) Proposals must address informed consent as well as assent if children, i.e., persons younger than 18 years of age will be involved in the research. (In Tennessee, children 16 years of age and older have the same rights regarding treatment, confidentiality, consent, etc. as adults (i.e., persons 18 years of age, the age of majority in our state). The informed consent document should, at minimum, include the following information:

a) Statement that the study involves research, the purpose of the research and the expected duration of the service recipient/participant's involvement in the research, a description of the procedures to be followed and identification of any procedures that may be experimental.

b) Proposals must address informed consent as well as assent if children, i.e., persons younger than 18 years of age will be involved in the research. (In Tennessee, children 16 years of age and older have the same rights regarding treatment, confidentiality, consent, etc. as adults (i.e., persons 18 years of age, the age of majority in our state). The informed consent document should, at minimum, include the following information:

c) Statement that the study involves research, the purpose of the research and the expected duration of the service recipient/participant's involvement in the research, a description of the procedures to be followed and identification of any procedures that may be experimental.

[1]Research ethics should specifically incorporate how the researcher(s) will obtain informed consent and protect the confidentiality of participants throughout the study period. A copy of all informed-consent forms for study participants and any other pertinent forms and assessment tools must be submitted at the time of the request.

d) Discussion of any foreseeable risks or discomforts to the subject.

e) Discussion of any benefits to the subject.

f) Disclosure of any alternative treatments that might be advantageous to the participant.

g) Statement indicating the extent to which confidentiality of the data will be maintained.

h) For research involving more than minimal risk, an

explanation of whether any compensation and medical treatment might be available to the subject if injury occurs, and if so, what compensation and/or medical treatment is available or where further information may be obtained.

i) Explanation of whom to contact for further information.

j) Statement that participation is voluntary and refusal to participate or discontinue participation at any time will not result in penalty or loss of benefits or services to which the service recipient/participant and/or his or her family is otherwise entitled.

6) In some cases, a Waiver of Consent/Authorization should be requested to address the issue of informed consent. Such a waiver would be necessary when disclosure or use of protected health information (PHI) involves minimal risk to the privacy of the research participants; the research could not practicably be done without the PHI; and the research could not practicably be done without the waiver. All waivers/authorizations must be accompanied by a signed Principal Investigator (PI) Assurance form confirming service recipient/participant welfare and rights will be observed and protected.

7) In other instances, consent/authorization may not be required. For example, when research is conducted using a limited data set under a data use agreement or only de-identified data is involved, a waiver is not required.

8) All initial requests to conduct research associated with the RMHIs must have written executive approval. Permission to conduct the research can be provided by the TDMHSAS Commissioner, the Assistant Commissioner of Hospital Services, and/or the Chief Officer for the RMHI or his/her designee. Written approval can be provided electronically or in hard copy.

9) Initial research submitted by some entity other than the PI must have written approval from the PI prior to review by the TDMHSAS IRB. Written approval can be provided electronically or in hard copy.

10) Initial research being conducted by a researcher affiliated with an academic institution must further provide institutional IRB approval prior to submission to the TDMHSAS IRB.

b. <u>Continuing Review</u> (Assumes exemption has been ruled out. See

Section III.B.6 on exempt research.)

1) Proposals undergoing continuing review have been previously approved by the TDMHSAS IRB and are still active/open. In most cases, service recipients/participants are still being enrolled/consented or followed-up in the research at the time of continuing review.

2) Continuing review may also involve research:

   a) That is permanently closed to new enrollees;

   b) In which all service recipients/participants have completed the interventions;

   c) For which active status only involves long-term follow-up of participants;

   d) In which no participants have been enrolled and no additional risks have been identified; and/or

   e) Where the remaining activities involve only data analysis.

3) Continuing review will be conducted at intervals appropriate to the degree of risk, but not less than once per year. The TDMHSAS further reserves the right to observe or engage a third party to observe the consenting process and the research.

c. Review of Amendments to Currently Approved Research (*Initial or Continuing*: *(Assumes exemption has been ruled out. See Section III.B.6 on exempt research.*)

1) It may become necessary for PIs/researchers to amend their research proposal. These amendments are typically associated with changes to the protocol. Sometimes the changes are minor and do not substantially alter the risk level of the study. However, changes can be substantive and result in significant changes in the risk level of the research. Nevertheless, any change requires an amendment(s) to the research proposal and IRB approval ***prior to*** implementation.

2) The PI should indicate the components of the research that are being amended and why. Amendments requiring changes to the protocol or forms should be so documented.

3) The TDMHSAS IRB will review amendments to currently approved research. The review may constitute a full review or an expedited review.

4) An amendment(s) cannot be implemented until IRB approval has been rendered.

5) Review dates and/or version/revision numbers on stamped documents for amendments will change. However, the expiration date will remain unchanged unless the amendment review is part of a continuing review.

E. Review Process.

1. Initial review, continuing review, or review of amendments may be conducted by the full Board or as few as a single TDMHSAS IRB member.

2. In most cases, reviews of research involving vulnerable populations such as children, prisoners, pregnant women, or services recipients at the RMHIs regardless the level of risk, will be conducted at a full Board meeting.

3. Expedited reviews will be restricted to minimal risk research where waivers of consent are appropriate and/or to amendments. However, it is possible that research eligible for expedited review will be reviewed during a full Board meeting.

4. Full Review (i.e., full Board meeting)

   a. The types of research which require full review by the TDMHSAS IRB include, but are not limited to:

      1) Research that requires access to identifiable PHI where the identifiers are to be included in the data maintained by the researcher; and

      2) Research that involves obtaining information through intervention or interaction with the individual other than those qualifying for exemption. (*See Section III.B.6 on exempt research.*)

   b. If the research requires full review, the IRB must determine that the following requirements are satisfied:

      1) The risks to the subjects are minimized.

      2) The risks to the subjects are reasonable in relation to anticipated benefits.

      3) The selection of subjects is equitable to the maximum extent

possible within the research design.

4) Women and members of minority groups are included as service recipients/participants unless it is determined that it is inappropriate with respect to the health of the subjects or the purpose of the research. The design of the research shall include an analysis of whether the variables being studied in the trial affect women or members of minority groups differently than other subjects.

5) When appropriate, written consent must be sought from each service recipient/participant or service recipients/participant's legally authorized representative. If consent is given by a legally authorized representative, the PI or person responsible for data collection should verify the relationship of the representative to the service recipient/participant.

6) The informed written consent process should be sufficiently detailed in documents submitted to the IRB. (Under certain circumstances, 45 CFR Part 46 allows waivers or alterations of informed consent. The IRB will adhere to appropriate authority regarding informed consent. For children, parental permission will be handled in the same manner as informed consent, unless otherwise waived by the Board. Assent will also be obtained from children as appropriate.)

7) Review documents should include adequate provisions for data monitoring to ensure the safety of service recipients/participants and the appropriate number of participants involved in the study.

8) Review documents should further ensure adequate provisions exist to protect the privacy of service recipients/participants and to maintain confidentiality of the data.

9) Review documents should include appropriate safeguards to protect the rights and welfare of the service recipients/participants from vulnerability to coercion.

c. Full review will require the presence of at least a quorum (majority) of the membership. Further, at least one member in attendance must be a nonscientist. Members will meet in person, face-to-face, and/or through a conference line. The meeting will be convened in a scheduled location at a scheduled time and the quorum (majority) should be in attendance during discussion and vote on each request (proposal) for review at the meeting.

d. Discussions and votes taken during the full review meeting will be recorded and included in minutes.

1) Members with conflicting interests must recuse themselves from voting.

2) Members will also have the opportunity to abstain during a vote. A member involved in only part of the proposal discussion will likely abstain from voting.

3) Members will vote to approve, approve with conditions, disapprove, table (postpone), close-out, suspend, and/or terminate research activities.

e. If conditional approval is recommended, conditions to be addressed by the PI will be delineated by the membership during the meeting.

f. The IRB Administrator will relay Board decision to the PI within ten (10) working days of the convened meeting. This decision may be communicated electronically and/or in hard-copy format.

g. If conditions are indicated, the PI will have up to thirty (30) days from receipt of the conditional requirements to satisfactorily address them.

h. Conditions of approval are typically reviewed by a single member, usually the IRB Administrator, and then discussed with the TDMHSAS-IRB Chairperson. On occasion, an additional member or two might be asked to review whether conditional requirements were satisfactorily met. The TDMHSAS-IRB Chairperson will determine if more than one reviewer is needed.

i. The reviewer(s) will have ten (10) working days from receipt of responses to conditions for review and reporting back to the TDMHSAS-IRB Chairperson.

j. Turnaround from the TDMHSAS-IRB Chairperson is typically a one- (1-) to two- (2-) day process. (The Co-Chairperson will fulfill this responsibility if the Chairperson is not available.)

k. Once the TDMHSAS-IRB Chairperson (or Co-Chairperson in the absence of the Chairperson) approves the decision of the reviewer(s), the IRB Administrator will have (10) working days to share results with the PI. This final decision may be provided electronically and/or in hard copy. TDMHSAS IRB's Adverse Event/Unanticipated Problem form will accompany each approval message or letter to the PI. This form should be used to report serious adverse events/unanticipated problems to the Board as stipulated in the Common Rule.

5. Expedited Review.

a. The TDMHSAS-IRB Chairperson or designee may elect to conduct

expedited review of submitted research proposals. Review under the expedited procedure gives full IRB authority to the reviewers, except the ability to disapprove the research (To disapprove research requires review by a fully convened TDMHSAS IRB.)

b. Requirements of informed consent are still applicable under the expedited review procedure. An expedited review must fulfill all review requirements contained in 45 CFR 46.111 and its subparts and any subsequent revisions and amendments.

c. The types of research which that may qualify for expedited review include research that presents no more than minimal risk to human participants and involves only procedures from one of the following categories:

1) Clinical studies of medical devices and drugs that do not require an investigational new drug or device exemption application;

2) Collection of blood samples by ear stick, heel stick, finger stick, or venipuncture that do not exceed specified amounts in an eight-week period or occur more often than twice weekly;

3) Prospective collection of biological specimens for research purposes by nonintrusive means;

4) Routine, nonintrusive data collection that is typically employed in clinical settings (Medical devices must be pre-approved for marketing);

5) Research involving de-identified or non-identifiable data, documents, records, or specimens that have been or will be collected solely for non-research purposes;

6) Data collection from voice, video, digital, or image recordings made for research purposes; or

7) Research on group or individual behaviors or characteristics like cultural beliefs or practices, social behavior, etc., or research that uses survey, interview, focus group, program evaluation, human factors evaluation, oral history, or quality assurance methods.

8) Exclusions from expedited review include research where participant identification and/or responses would reasonably place participants at risk of criminal or civil liability or be damaging to them as well as classified research. (Expedited review may be used if risks associated with invasion of privacy and breach of confidentiality would be minimized.)

d. Expedited review will typically involve a single member, usually the IRB Administrator. One or more IRB members may be involved in the review, but not the full Board. Reviewers cannot have a conflicting interest in the request (proposal).

e. Expedited review will follow the same process and time frame as full review.

f. If review warrants a Waiver of Consent/Authorization, the waiver form and accompanying PI Assurance Form must be completed.

g. Reviewer decisions involving the Waiver of Consent/Authorization and PI Assurance Form are handled in the same way as decisions for full review. The adverse event/unanticipated problem form is also shared for reporting purposes, if appropriate.

6. Exempt Research

a. The TDMHSAS-IRB Chairperson or designee may exempt a study from full or expedited review.

b. Research qualifying for exemption may include the following:

1) Research conducted in established or commonly accepted educational settings involving normal educational practices such as research on regular or special education instructional strategies;

2) Research involving the use of educational tests if data are recorded in such a manner that subjects cannot be identified;

3) Research involving survey or interview procedures except where responses include a participant's identification and his or her responses could reasonably place the participant at risk of criminal or civil liability; damage the participant's financial status, employability, or reputation; or include sensitive aspects of the participant's behavior;

4) Research involving survey or interview procedures when the subject is an elected official or appointed public official, or candidate for public office;

5) Research involving the observation of public behavior except where the service recipient/participant can be identified and his or her responses could reasonably place the service recipient/participant at serious risk;

6) Research involving the collection or study of existing data documents, records, pathological specimens or diagnostic specimens if the sources are publicly available or the participants cannot be identified;

7) Unless specifically required by statute, research and demonstration projects subject to the approval of or conducted by the United States Department of Health and Human Services (DHHS) and designed to study programs under the Social Security Act or other public benefit service programs; to study procedures for obtaining benefits or services of those programs; to study changes in or alternatives to those programs; or to study changes in the methods or levels of payment for services or benefits under those programs.

8) Consumer acceptance studies and food and taste quality evaluations if wholesome foods without additives are consumed, if food is consumed that contains a food ingredient below or at the level and for a use found to safe, or environmental contaminant or agricultural chemical at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Department of Agriculture's Food Safety and Inspection Service.

F. Failure to Submit Research for IRB Review

1. The IRB does not actively set out to penalize prospective researchers, including TDMHSAS staff, for failing to submit projects for review. However, research that meets requirements indicated in Section II.A.2 of this document must come through the TDMHSAS IRB for review.

2. It should also be noted that many peer-reviewed journals will not allow publication unless IRB approval was obtained prior to data collection.

3. The TDMHSAS IRB reserves the right to refuse review of proposals that were not submitted in advance of actually conducting the research study. Exceptions to this right to refusal might include research studies in which the welfare or rights of participants could have been jeopardized and/or the data were collected for non-research purposes but currently the PI/researcher has plans to submit an article for publication.

IV. Procedure for Activities Subject to IRB Review

Procedure:

This procedure provides guidance on how to prepare and submit research for review and approval by the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB).

1. Principal Investigator (PI) Responsibilities

   a. *Initial Review (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

      1) Instructions for submitting initial review requests to conduct research (proposals) are available on the TDMHSAS-IRB Web page: http://tn.gov/assets/entities/behavioral-health/attachments/CL-IRB_Proposal_Instructions.pdf.

      2) A separate request is required for each study submitted for IRB review. Proposal content and flow are described in Section III.A.4.a. of this manual. A suggested, formatted proposal is available on the TDMHSAS Web site at http://tn.gov/assets/entities/behavioral-health/attachments/Suggested_IRB_Proposal_Format.pdf and is further included in the appendices of this manual. The researcher's document or sponsor's protocol may be used to submit the proposal (request) if it contains all required elements.

      3) Any activities to be carried out by TDMHSAS staff should be delineated in the request.

      4) Proposals may receive full or expedited review. Processes and time frames will adhere to policy for initial review.

      5) The IRB Administrator will conduct a brief review of each submitted proposal to determine if it contains required materials, e.g., a cover letter. ***However, it is the responsibility of the Principal Investigator to ensure the accuracy and completeness of submitted proposals***.

      6) Sometimes initial review will involve submission of a Waiver of Consent/Authorization and PI Assurance Form. Submission will follow the initial review processes and time frames.

   b. *Continuing Review (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

1) Instructions for submitting continuing review requests (proposals) are available on the TDMHSAS-IRB Web page: http://tn.gov/assets/entities/behavioral- health/attachments/CL-IRB_Proposal_Instructions.pdf.

2) Proposals may receive full or expedited review. Processes and time frames follow initial review.

3) Waiver of Consent/Authorization and/or PI Assurance Forms may require resubmission but follow initial revie10w processes and time frames.

c. *Review of Currently Approved Research by Amendment (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

1) Amendments can be submitted any time.

2) Information regarding the purpose of the amendment(s) should be delineated. Specifically discuss any changes to risk level as a result of the amendment(s).

3) Submit copies of forms, questionnaires, and/or other documents that would be affected by the amendment request. Submit new forms/documents if so dictated by the amendment(s).

4) Amendments may receive full or expedited review. Processes and time frames follow initial review.

2. IRB Review Process.

a. *Initial Review (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

1) The IRB Administrator will distribute materials for review to appropriate members, as determined by whether the initial review is full or expedited. Typically materials will be distributed electronically via secure email. Every reasonable effort will be made to distribute materials in a timely fashion.

2) Review will follow the appropriate processes. The review time frames will follow that delineated in policy.

3) Full or expedited initial review can be conducted for studies involving a Waiver of Consent/Authorization and PI Assurance Form. Processes and time frames will adhere to the appropriate policy.

4) The membership will determine if date of receipt warrants review

consideration for the current month's meeting. In some cases, the proposal may be tabled until the next scheduled TDMHSAS-IRB meeting.

5) The IRB Administrator, in conjunction with the Chairperson (Co-Chairperson in the absence of the Chairperson), will determine if a waiver request with PI assurances requires full or expedited review.

6) Membership will be informed regarding outcomes of all initial reviews.

b. *Continuing Review (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

1) The IRB Administrator will distribute materials for review to appropriate members, as determined by whether the continuing review is conducted by the full Board or expedited. Typically materials will be distributed electronically via secure email. Every reasonable effort will be made to distribute materials in a timely fashion.

2) Review will follow the appropriate processes. The review time frames will follow that delineated in policy.

3) Full or expedited continuing review can be conducted for studies involving a Waiver of Consent/Authorization and PI Assurance Form. Processes and time frames will adhere to the appropriate policy.

4) Membership will be informed regarding outcomes of all continuing reviews.

c. *Review of Currently Approved Research by Amendment (Assumes exemption has been ruled out. See Section III.B.6 on exempt research.)*

1) The IRB Administrator will distribute materials for review to appropriate members, as determined by whether the amendments will be reviewed by the full board or expedited. Typically materials will be distributed electronically via secure email. Every reasonable effort will be made to distribute materials in a timely fashion.

2) Review will follow the appropriate processes. The review time frames will follow that delineated in policy.

3) Membership will be informed regarding outcomes of all amendments.

3. IRB Responsibilities.

a. The TDMHSAS IRB shall, through its operations, protect the welfare and rights of service recipients/participants involved in research

activities.

b. The TDMHSAS IRB shall maintain a valid FWA, as well as an approved IRB status.

c. The TDMHSAS IRB shall not operate with fewer than five (5) members. Membership must include at least one member from the following categories: a non- scientist; staff at an RMHI or Hospital Service division central office staff; someone not affiliated with the department as staff; and someone who can represent the service recipient/participant community. It should be noted that the aforementioned categories do not need to be mutually exclusive.

d. Decisions regarding proposals, including amendments, will follow the processes and time frames delineated in policy.

e. The business of the TDMHSAS IRB shall be accessible to authorized representatives or designees of the Office for Human Research Protections (OHRP) or other appropriate Federal agencies at reasonable times and in a reasonable manner.

V. Policy on Administrative Hold, Expiration, Suspension, or Termination of IRB Approval

Policy:

Unless otherwise indicated, it is the policy of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) to approve research for a period not to exceed one year. The Board further recognizes that all currently approved research is subject to change or modification in approval status and, as a result, may ask the PI to put the research on administrative hold until additional information has been obtained. Administrative holds constitute an action to temporarily or permanently stop, at minimum, some research activities in modification to approved research. They are not considered suspensions or terminations, and do not meet reporting requirements to OHRP and other federal agencies. The IRB may also suspend or terminate research if there is evidence that the research is not being conducted in accordance with the IRB's requirements or the Federal regulations or if the research has been associated with unexpected serious harm to participants. Examples leading to suspension might include:

1. Inappropriately involving human subjects in research.

2. Inhibiting the rights or welfare of participants.

3. Serious or continuing noncompliance with Federal regulations or IRB policies.

4. New information indicating increased risk to human participants, etc.

A. Administrative Hold.

1. The IRB may ask the PI to put some or all research activities on hold until additional information can be obtained in order to determine if a change in the risk-potential benefit has occurred, if a change in the welfare or rights of the participants has occurred, or if potential areas of noncompliance exist in a currently approved research protocol. Evidence to support this request may occur through a variety sources including:

   a. A complaint received by the TDMHSAS IRB.

   b. An allegation of noncompliance to the IRB.

   c. A discovery by the PI of potential additional risks.

   d. IRB deliberations.

2. The IRB notifies the PI in writing of its request for "Administrative Hold", the time frame for responding, and the specific requested activities to be put on hold.

3. If the PI does not respond within the IRB's requested time frame, the study may be suspended and/or appropriate sources, including the Commissioner and the study's sponsor will be notified.

4. The TDMHSAS-IRB Chairperson and/or the IRB can choose instead to recommend additional education and/or compliance interventions for the PI and his or her key study personnel through the TDMHSAS-IRB Chairperson.

5. If the additional information indicates that no change to the risk-potential benefit has occurred, the welfare or rights of participants has not been compromised, and/or the issue of noncompliance has been ruled out, the IRB through the IRB Administrator (IA) will notify the PI that the study may return to active status. Otherwise, the matter will be referred to the convened IRB.

6. The research remains subject to continuing review and requirements for reporting non- compliance and unanticipated problems/adverse events involving risks to participants or others when a study has been placed on administrative hold.

B. Study Expiration.

1. When a PI fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the specified expiration date, the study expires. This means that enrollment of new participants cannot occur and all research activities must stop.

2. PIs should be notified regarding IRB actions around an expired study. The Board can institute a “grace period” and/or request that enrollment of new participants cease and/or all research activities stop.

3. If expiration becomes official, the PI must immediately submit to the IRB a list of research participants for whom stopping the research would cause harm.

4. Once the list is received, the IRB will review and determine for which individual participants continuing to participate in the research is in their best interest.

5. Research studies not reviewed and approved within ninety (90) days of the date of expiration must be administratively closed by the IRB. Reinstatement of the research will require submission of a research proposal for initial review.

C. Suspensions.

1. Suspensions can be initiated by a sponsor or the IRB.

2. Sponsor-initiated suspensions are likely related to risk involving the potential for unanticipated problems with increased risk to participants.

3. The IRB’s suspension typically involves placing a temporary interruption or stop of some or all currently approved research activities for concern regarding the rights, safety, or welfare of service recipients/participants, investigators, or others pending one or more corrective actions or events.

4. Any suspensions should be communicated to the PI in writing, with explanations of the IRB's action.

5. The PI should submit proposed procedures for withdrawing currently enrolled service recipients/participants, for IRB review. Procedures should incorporate a script/letter notifying the service recipients/participants of the suspension. The IRB can decide how follow-up will be handled and whether oversight/transfer of responsibility for implementing the procedures to another Investigator would be more appropriate.

D. Terminations.

1. A researcher may request termination of a study when it has not been possible to begin research activities. For example, a researcher may not be able to secure service recipient/ participant involvement in the research and request termination.

2. The IRB may decide to terminate a study for safety reasons. For example, the risks may start to outweigh any benefits.

3. The IRB, in consultation with appropriate institutional officials, must determine whether follow-up should continue or cease in a terminated study.

4. Decisions will be communicated to the PI in writing. PI contact (written and/or face-to- face) with current service recipients/participants must have IRB approval.

5. Any unanticipated serious adverse events or unanticipated problems involving risks to service recipients/participants or others must be reported to the appropriate sources, such as the IRB, sponsor, OHRP.

VI. Procedure for Administrative Hold, Expiration, Suspension, or Termination of IRB Approval

Procedure:

This procedure provides guidance on how the of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) will institute administrative holds, suspensions, and/or terminations of IRB approval.

G. Administrative Hold.

1. The IRB may impose an administrative hold on research activities per policy. (See Section V.A.1.)

2. Failure to adhere to conditions of the administrative hold may result in stronger actions such as training and/or suspension of the research.

H. Study Expiration.

1. Review documents are stamped with an expiration date that is equivalent to not more than one year from the date of IRB approval. (Expiration dates do not change for amendment approvals.)

2. The IRB Administrator may notify the PI/researcher of an upcoming expiration date. However, it is the responsibility of the PI/researcher to submit materials for continuing review in advance of the stamped expiration date.

3. Failure to submit continuing review requirements in advance of the stamped expiration date will result in action by the IRB, which could include suspension of research activities.

4. The study will receive administrative closure if review and approval not met within 90 days of the stamped expiration date.

I. Suspensions.

1. Suspensions may result as per policy. (See Section V.C.)

2. PIs/researchers will be notified in writing. Notification will include details around the IRB's actions.

3. Suspensions may be simple or very complex. IRB actions will be based on protections of the rights and welfare of service recipients/participants.

J. Terminations.

1. Unfulfilled research will be terminated, typically at the request of the PI/researcher. This involves research that never started.

2. Severe adverse events/unanticipated problems that are related to research activities and whose risks outweigh benefits may be terminated by the IRB.

3. Appropriate notifications, which may include the study sponsor and/or OHRP, will be submitted in writing.

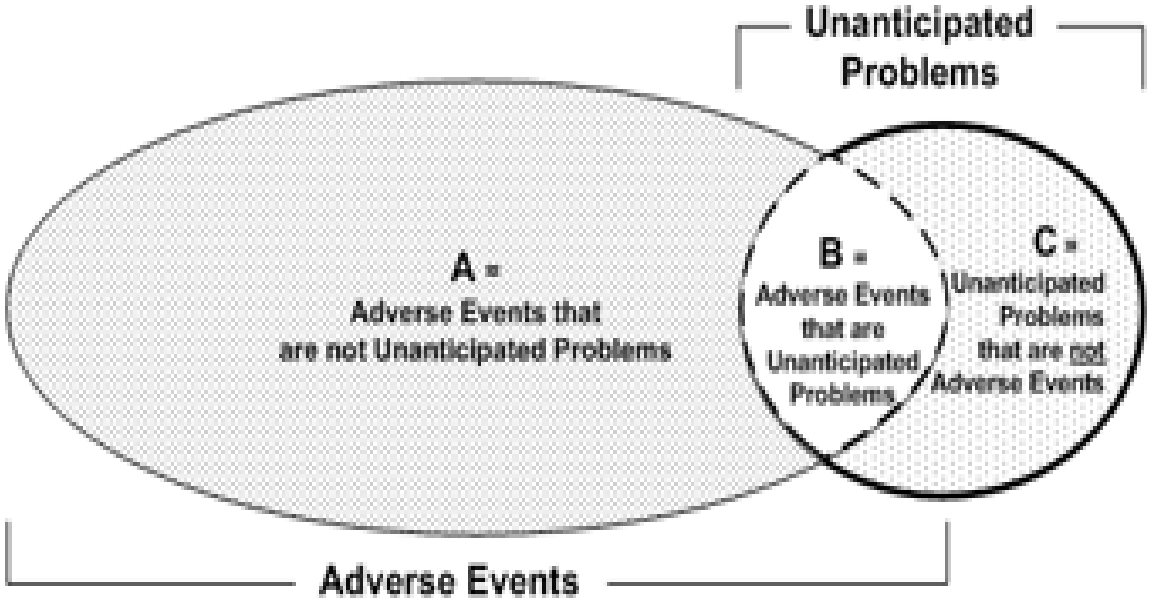
VII. Policy on Reporting Unanticipated Problems and Adverse Events Involving Risk to Service Recipients/Participants or Other Entities

Policy:

It is the policy of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Institutional Review Board (IRB) to require documentation and/or reporting of unanticipated problems/adverse events.

A. Definition of Unanticipated Problems/Adverse Events

1. The diagram below shows the relationship between adverse events and unanticipated problems.



Source: *Taken from OHRP Guidance, 2007.*

2. Per OHRP, unanticipated problems incorporate any experience, incident, or outcome that that meets ***all*** three of the following criteria:

   a. The problem is unexpected. It was not expected given the research procedures described in the informed consent document and/or the IRB-approved research protocol. Neither was the problem expected given the characteristics of the service recipient/participant-population under study. The unexpectedness may relate to how the problem occurred, how often

the problem occurred, or to the extent at which the problem occurred.

b. The problem is related or possibly related to a service recipient/participant's participation in the research. "Possibly related" indicates there is a reasonable likelihood that the experience, incident, or outcome may have been caused by the procedures involved in the research. If it is determined that an event is solely caused by an underlying condition, disease, or disorder of the service recipient/participant *OR* other circumstances not related to either the condition, disease, or disorder of the service recipient/participant or the research, then the event would be considered unrelated to participation in the research.

c. The research places the service recipients/participants or others at a greater risk of harm than was previously recognized or known. "Harm" can include economic, psychological, physical, or social harm. Moreover, this harm needs to be serious such as causing the service recipient/participant to move to a higher level of care or the service recipient/participant dies. If a death occurs, it must be related to the research.

3. Unanticipated problems are reportable to OHRP, whether or not they are adverse events.

4. Adverse events are neither defined nor used in 45 CFR part 46, but broadly encompass both physical and psychological harm. The harm must be serious and related to the research.

5. Most adverse events are not unanticipated problems, as shown in Area A of the diagram on the preceding page. Such events are not reportable to OHRP under 45 CRF 46, but may be reported to the IRB.

6. Area B includes adverse events that are additionally unanticipated problems. These events must be reported to the IRB, who will, in turn, report to OHRP. (It is the responsibility of the PI to report these events to the sponsor. Often action, such as suspension of research, takes place when these type of events occur.

7. Area C in the above diagram shows unanticipated problems that are not adverse events. These problems tend not to fit the typical definition of adverse event, but might, in the opinion of the PI, involve risk to the service recipients/participants, affect others in the research study, or significantly impact the integrity of the research data such as accidental destruction of study records, breaches of confidentiality, or unaccounted-for study drug Such events often warrant consideration of substantive changes in the informed consent process/document, research protocol, or other corrective actions in an effort to protect the rights, safety, or welfare of service recipients/participants or others.

8. All adverse events or unanticipated problems must be documented by the PI/researcher.

B. Responsibilities When Unanticipated Problems/Adverse Events Occur

1. Unanticipated problems must be reported to the IRB even after service recipients/participants have completed the study or after withdrawal from the study including after study closure.

2. The PI should submit an adverse event/unanticipated problem form for each individual service recipient/participant to the IRB. Adverse events/unanticipated problems should be incorporated into continuing review proposals.

3. Any adverse event/unanticipated problem must be reported to the IRB. The IRB Administrator, in conjunction with the IRB Chairperson, will determine whether the event/problem needs full IRB review.

4. Serious adverse events such as death of a service recipient/participant, whether or not the incident is determined to be related to the research, must be addressed at a full IRB meeting.

5. Communication with the PI regarding adverse events/unanticipated problems will be conducted in writing.

VIII. Procedure for Reporting Unanticipated Problems and Adverse Events Involving Risk to Participants or Other Entities

Procedure:

This procedure outlines the process for reporting of unanticipated problems and/or adverse events that involve risk to participants or other entities.

A. Responsibilities of the PI

1. The PI is responsible for accurate documentation, investigation, and/or follow-up related to adverse events/unanticipated problems.

2. The PI should report any non-fatal adverse event, whether or not the incident is determined to be an unanticipated problem, to the IRB Administrator within ten (10) working days of his or her knowledge of the

situation.

3. The PI shall submit a completed TDMHSAS-IRB Unanticipated Problem/Adverse Event Form for the non-fatal adverse event/unanticipated problem. This form is provided to each PI upon approval of his or her initial or continuing review study.

4. The PI should report any serious (i.e., life threatening or fatal) adverse event, whether or not the incident is determined to be an unanticipated problem, to the IRB Administrator within 48 hours of his or her knowledge of the situation.

5. The PI shall submit a completed TDMHSAS-IRB Unanticipated Problem/Adverse Event Form within five (5) working days of his or her knowledge of the situation. This form is provided to each PI upon approval of his or her initial or continuing review study.

6. The PI should reference the adverse event, whether or not the incident is determined to be an unanticipated problem, in the continuing review proposal.

B. IRB Chairperson/IRB Administrator (IA) Responsibilities

1. The IRB Administrator, in conjunction with the IRB Chairperson (or Co-Chairperson in the absence of the Chairperson), receives and reviews reports of adverse events/unanticipated problems submitted on the TDMHSAS-IRB Unanticipated Problems/Adverse Events Form.

2. The IRB Administrator (IA) will schedule serious adverse events such as death of a service recipient/participant, whether or not the incident is determined to be related to the research, for full IRB review.

3. Current PI action will be accepted or additional action will be attached to other incident reports. These actions will be communicated in writing to the PI.

4. The IA will further remind the PI about any necessary contacts with the sponsor.

C. IRB Responsibilities

1. When the event is an unanticipated problem, the IRB may postpone its decision while awaiting additional information. In such cases, the IRB may consider the appropriateness of an “Administrative Hold” on the research until a final determination is made.

2. When the event is an unanticipated problem, the IRB can take one or more of the following actions:

   a. Continue the study as originally submitted and approved. No changes are needed.

   b. Approve actions taken by the PI.

   c. Accept changes in the protocol and/or consent form(s) recommended by the PI.

   d. Require different and/or additional changes in the protocol and/or consent form(s).

   e. Report the unanticipated problem OHRP.

   f. Suspend some or all research activities. Discuss this option with the PI and document the discussion.

   g. Terminate the study. Terminate the study Discuss this option with the PI and document the discussion.

3. When the event is an unanticipated problem, the IRB decision will be recorded on the appropriate Unanticipated Problem/Adverse Event Form and indicated in meeting minutes. The IRB Chairperson will sign and date the decision, as well as any other additional information that the IRB recommends be shared with the study's PI.

4. When the event is a serious adverse event unrelated to participation in research, the IRB will be apprised of conditions for that study. The IRB may or may not elect to increase the number of continuing reviews during a research year.

REFERENCES

- 42 Code of Federal Regulations (CFR) Part 2
- 45 CFR 46
- 42 CFR 50 Subpart A-E
- 45 CFR 160 and 164
- Cohen, J.M. (2007). Program evaluation & IRB review. HRP Associates, Inc. http://rbhs.rutgers.edu/hsp/education/06_2007/HSPP_Conf_Program%20Evaluation_06.2007_NWK.pdf
- Office of Human Research Protections (OHRP) Guidance on Written IRB Procedures, 2011 - http://www.hhs.gov/ohrp/policy/irbgd107.pdf
- OHRP Guidance on Continuing Review, 2010 - http://www.hhs.gov/ohrp/policy/continuingreview2010.html
- OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, 2007 - http://www.hhs.gov/ohrp/policy/advevntguid.html
- OHRP FWA Informational Web site - http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html
- OHRP Training/Educational Web site - http://www.hhs.gov/ohrp/education/training/
- Providers' Clinical Support System (PCSS) Web site
- Schwenzer, K.J. (2008) Protecting vulnerable subjects in clinical research: Children, pregnant women, prisoners, and employees. Respiratory Care, 53(10), 1342-1349.
- Substance Abuse and Mental Health Administration Services (SAMHSA) News. (2016, February 24). Comment on records confidentiality rule.
- TDMHSAS Web page
- TDMHSAS IRB Policy Number 05-01
- TDMHSAS IRB Web page
- Tennessee Code Annotated (TCA) Title 33
- The Belmont Report - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

GLOSSARY

Definitions

- **De-identified Data**. Data that minimizes the probability of misuse of protected health information (PHI) such that service recipient privacy is maintained. Often identifiers have been removed so that individuals cannot be identified at the person level. Typically the data are encrypted. It is not completely anonymous information because re-identification remains a possibility when analyzed in conjunction with other data. Also referred to as non-identifiable data.

- **Designee**. Any TDMHSAS IRB member that the Chairperson appoints to perform duties in his or her stead.

- **Identifiable Data**. Information that can either directly or indirectly lead to the identification of an individual. Examples of such data are name, social security number, health insurance number, etc. Indirect identification of individuals typically occurs through combining "sensitive" information such as date of birth and postal zip code.

- **Interaction**. Communication or interpersonal contact between the researcher and the person consenting to participation in the research study.

- **Intervention**. Performing physical procedures or manipulating the participant or his or her environment for research purposes.

- **Non-identifiable Data**. See De-identified Data above.

- **Participant.** A human subject who consents to participate in a research activity.

- **Principal Investigator** (PI). The person primarily responsible for the scientific and ethical considerations of the research. This individual may also be referenced as the researcher. In many instances, the person has oversight for the total project--program and evaluation activities. Sometimes the research is carried out by a subcontractor or collaborator. There may also be situations when more than one person has primary responsibility for the research, such as the case of co-researchers. Typically the term PI and researcher are used interchangeably.

- **Privacy**. A person's right to restrict access to information, including Protected Health Information (PHI), about him/herself.

- **Protected Health Information** PHI). Information that is, but may not be limited to: information about the mental or physical health of an individual; information that references any health service provided to an individual; information related to the donation of any body part or any bodily substance by an individual; information collected in the provision of health services to an individual; or information incidentally collected in the provision of health services to an individual.

- **Researcher**. See definition of Principal Investigator (PI) above.

- **Service Recipient**. An individual who is receiving services, has applied for services, or for whom someone has applied for or proposed services because the individual has a serious emotional disturbance, mental illness, or a developmental disability.

APPENDICES

APPENDIX A

Suggested Research Proposal Format Document

TDMHSAS IRB Research Proposal Format

<Study Name Abbreviated>

Protocol Title

Type of Review: ☐ Initial ☐ Continuing Review ☐ Amendment

Study Team Personnel

Principal Investigator

Name:	
Degree(s):	☐ M.D. ☐ Ph.D. ☐ M.S. ☐ B.S. ☐ Other, specify:
Job Title:	
Affiliation:	
Human Subjects Training Completed:	☐ Yes ☐ No
Mailing Address:	
Phone:	
Fax:	
E-mail:	

<Co-Principal Investigator or Evaluator>

Name:	
Degree(s):	☐ M.D. ☐ Ph.D. ☐ M.S. ☐ B.S. ☐ Other, specify:
Job Title:	
Affiliation:	
Human Subjects Training Completed:	☐ Yes ☐ No
Mailing Address:	
Phone:	
Fax:	
E-mail:	

Additional Study Personnel

Research Staff/Personnel	Title/Role	Intervening/ Interacting with subjects?	Obtaining consent?	Review of data analysis and data records?	Completed human subjects training?
Name: Affiliation: Phone: Email:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Name: Affiliation: Phone: Email:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Name: Affiliation: Phone: Email:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

TDMHSAS IRB Research Proposal Format

<Study Name Abbreviated>

Research Staff/Personnel	Title/Role	Intervening/ Interacting with subjects?	Obtaining consent?	Review of data analysis and data records?	Completed human subjects training?
Name: Affiliation: Phone: Email:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Name: Affiliation: Phone: Email:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Funding Information and Grant Partners

Purpose of this Institutional Review Board Application

Research Protocol

Objectives

Hypotheses/Research Questions

Design

Population

Data Collection and Storage Procedures

TDMHSAS IRB Research Proposal Format

<Study Name Abbreviated>

Methods

Statistical/Data Analysis Plan

Summary of Risks

Summary of Benefits

Principal Investigator Assurance Statement(s)

<Signature of Principal Investigator> <Date of Signature>

<Name of Principal Investigator>

FOR OFFICE USE ONLY

Receipt Date: ___/ ___ /20___

Review: ☐ Full ☐ Expedited ☐ Exempt

Review Date: ___/ ___ /20___

Decision: ☐ Approved ☐ Approved with conditions
☐ Not approved/re-submit

IRB Administrator Initials: ____

APPENDIX B

Unanticipated Problem/Adverse Event Report Form

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

TENNESSEE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES (TDMHSAS)
Institutional Review Board (IRB)
Unanticipated Problem/Adverse Event Form

- Research Study Title: Click here to enter text.
- Research Study's Principal Investigator: Click here to enter text.
- Source of Funding/Sponsorship for the Research Study (If applicable): Click here to enter text.

Definition of an Unanticipated Problem

Per the U.S. Department of Health and Human Services, Office of Human Research Protections (OHRP), an unanticipated problem includes any experience, incident, or outcome that meets each of the criteria indicated below.

(1) The problem is unexpected. It was not expected given the research procedures described in the informed consent document and/or the IRB-approved research protocol. Neither was the problem expected given the characteristics of the participant-population under study. The unexpectedness may relate to how the problem occurred, how often the problem occurred, or to the extent at which the problem occurred.

(2) The problem is related or possibly related to a participant's being a part of the research. "Possibly related" indicates there is a reasonable likelihood that the experience, incident, or outcome may have been caused by the procedures involved in the research.

(3) The research places the participants or others at a greater risk of harm than was previously recognized or known. "Harm" can include economic, psychological, physical, or social harm.

echappel/TDMHSASResearchTeam *Created: 12/21/2012* *Revised: n/a*

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

Definition of an Adverse Event

An adverse event must meet the following definition: "Any unfavorable or untoward medical occurrence in a human participant, including any abnormal sign (for example, laboratory finding or abnormal physical exam), disease, or symptom, temporally associated with the participant's involvement in the research, whether or not considered related to the participant's participation in the research." This definition is a modification of "adverse events" as found in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice. An adverse event occurs most frequently in the context of biomedical research, though it can occur in the context of behavioral and social research.

- **Which of the following criteria describe the unanticipated problem/adverse event addressed in this report?** *Note: Per ***OHRP Guidance*** (link to document located at end of this form), the incident, experience, or outcome should meet all three criteria to warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

  ☐ Unexpected

  ☐ Related or possibly related to participation in the research

  ☐ Research places subjects/others at greater risk of harm than previously recognized or known

- **Detailed Description of the Nature of the Unanticipated Problem/AdverseEvent**

  1. The unanticipated problem/adverse event was unanticipated.

     Click here to enter text.

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

- **Detailed Description of the Nature of the Unanticipated Problem/AdverseEvent** (continued)

  2. The unanticipated problem/adverse event was related or possibly related to the study.

     Click here to enter text.

  3. The unanticipated problem/adverse event placed subjects/others at greater risk of harm than previously recognized or known.

     Click here to enter text.

- Date Principal Investigator learned about the unanticipated problem/adverse event indicated in this report. Click here to enter a date.

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

Principal Investigator Actions Taken on the Unanticipated Problem/Adverse Event

☐ Reported unanticipated problem/adverse event to lead agency: Click here to enter a date.

☐ Reported unanticipated problem/adverse event to provider agency: Click here to enter a date.

☐ Reported unanticipated problem/adverse event to funding/sponsoring agency (optional): Click here to enter a date.

Principal Investigator Recommendations for the Unanticipated Problem/Adverse Event

☐ Continue study as submitted and approved by IRB. No changes needed.

☐ Make changes in protocol and/or consent form. (See attached.)

☐ Suspend some or all research activities.

☐ Terminate the study.

I affirm that statements and actions indicated in this report are accurate.

_____ _____

Signature of Principal Investigator Date

_____

Printed Name of Principal Investigator

echappel/TDMHSASResearchTeam *Created: 12/21/2012* *Revised: n/a*

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

TDMHSAS IRB Actions Taken on the Unanticipated Problem/Adverse Event
(TDMHSAS IRB Use Only)

☐ Continue study as originally submitted and approved. No changes needed.

☐ Approve actions taken by Principal Investigator.

☐ Accept changes in protocol and/or consent form recommended by Principal Investigator.

☐ Require different and/or additional changes in protocol and/or consent form.

☐ Report unanticipated problem/adverse event to the Office of Human Research Protections (OHRP).

☐ Suspend some or all research activities. Discuss with Principal Investigator.

☐ Terminate the study. Discuss with Principal Investigator.

_____ _____

Signature of IRB Chairperson Date

_____

Printed Name of IRB Chairperson

TDMHSAS IRB
Unanticipated Problem/Adverse Event Report Form (FINAL Version)

Information requested through this form is based on *Guidance on Reviewing and Reporting* http://www.hhs.gov/ohrp/policy/advevntguid.html.

APPENDIX C

Waiver of Consent/Authorization Form

Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS)
Institutional Review Board (IRB)
Waiver of Consent/Authorization Form

Please provide adequate information to each question for consideration of approval of the request for a waiver of consent/authorization.

1. The research and privacy risks are no more than minimal.

2. The research could not be practically conducted without waiving the consent/authorization process.

3. The research requires access to and use of Protected Health Information (PHI) to conduct this study. Also, discuss how the PHI will be used, as well as its handling after data collection.

4. The waiver will not adversely affect the welfare or rights of the participants.

5. When appropriate, the research participants will be provided with additional pertinent information after participant. (*Note*: *Use N/A when question is not relevant.*)

☐ TDMHSAS Approval of the Waiver of Consent/Authorization

☐ TDMHSAS Disapproval of the Waiver of Consent/Authorization

_____ _____

Signature of TDMHSAS IRB Chairperson/Designee Date

echappell/TDMHSAS IRB *Created: 01/20/2014* *Revised: N/A*

APPENDIX D

Principal Investigator Assurances Form

Principal Investigator Assurances
Related to
Waiver of Consent/Authorization

As Principal Investigator for the _____ *<Insert Name of Your Study Here>* _____ study,

1. I will ensure the privacy and confidentiality of the participants in this study for whom this Waiver of Consent/Authorization is approved.

2. I verify that protected health information (PHI) collected for this study will be protected from improper disclosure and use.

3. I will ensure proper storage of protected health information (PHI) collected for this study until such time as the data are fully de-identified and/or destroyed.

4. I will not disclose or re-use the protected health information (PHI) collected for this study to any individuals or entities, except as required by law or authorized in the conduct of this research.

5. I understand that improper use or disclosure of protected health information (PHI) or failure to safeguard the privacy and security of the PHI may result in civil and/or criminal penalties and employment disciplinary action if applicable.

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of TDMHSAS IRB Chairperson/Designee Date

APPENDIX E

Document Translation Requirements

Document Translation Requirements

Researchers sometimes need to prepare consent forms and other documents in languages other than English due to the diversity of their participants. Thus, the consent forms/other documents need to be written in Spanish or other languages so participants can read them and make an informed decision about participation in the research project.

At the May 20, 2016, meeting, the TDMHSAS IRB voted that researchers must have documents written in languages other than English translated by a certified translator or an affidavit of translation/certification of accuracy. Therefore, all new proposals for review by the TDMHSAS IRB that submit translated documents must ensure those documents meet this requirement and provide documentation that the requirement has been met.

To assist researchers in meeting this requirement, the TDMHSAS IRB has identified a sample of translation services in East, Middle, and West Tennessee, as well as an online resource. Contact information for those services is indicated below. Additionally, the TDMHSAS IRB has listed all colleges and universities in the state that may have a translation program and hence may provide translation services. That list is also shown below.

Sample List of Translation Services

- AAA Translators, Memphis, TN, 901-372-7373
- ACS, Franklin, TN, 615-591-7838
- Corporate Spanish of Knoxville, Knoxville, TN, 865-777-1177
- Gate Communications, Franklin, TN, 615-435-8929
- Language Marketplace, 125 N Main St, Memphis, TN 38103, 888-294-3032
- Nashville Interpreters, Nashville, TN, 615-419-5103
- Nashville Languages Inc. Translation Company, Nashville, TN, 615-485-4588
- Visual Communication Interpreting, Knoxville, TN, 865-622-0999
- www.rev.com, Online Service, 888-369-0701

Contact Information
Tennessee Colleges and Universities

Rhodes College
2000 North Parkway, Memphis, TN 38112-1690, 901-843-3000

Vanderbilt University
2101 West End Avenue, Nashville, TN 37240, 615-322-7311

Sewanee: The University of the South
735 University Avenue, Sewanee, TN 37383-1000, 931-598-1000

Milligan College
1 Blowers Blvd, Milligan College, TN 37682, 423-461-8700

Martin Methodist College
433 West Madison Street, Pulaski, TN 38478-2799, 931-363-6090

Bryan College
721 Bryan Drive, Dayton, TN 37321-7000, 423-775-2041

Maryville College
502 E Lamar Alexander Pky, Maryville, TN 37804-5907, 865-981-8000

Cumberland University
One Cumberland Square, Lebanon, TN 37087, 615-444-2562

Tennessee Temple University
1815 Union Ave, Chattanooga, TN 37404, 423-493-4100

Hiwassee College
225 Hiwassee College Drive, Madisonville, TN 37354-4001, 423-442-2001

The University of Tennessee
527 Andy Holt Tower, Knoxville, TN 37996, 865-974-1000

Belmont University
1900 Belmont Blvd, Nashville, TN 37212-3757, 615-460-6000

Union University
1050 Union University Dr, Jackson, TN 38305-3697, 731-668-1818

Middle Tennessee State University
1301 East Main Street, Murfreesboro, TN 37132, 615-898-23000

Tennessee Technological University
1 William L. Jones Drive, Cookeville, TN 38505-0001, 931-372-3223

University of Memphis
Memphis, TN 38152, 901-678-2000

Freed-Hardeman University
158 E Main St, Henderson, TN 38340-2399, 800-348-3481

Lipscomb University
One University Park Drive, Nashville, TN 37204-3951. 615-966-1000

The University of Tennessee-Martin
554 University Street, Martin, TN 38238-0002, 731-881-7000

Southern Adventist University
4881 Taylor Cir, Collegedale, Tennessee 37315-0370, 423-236-2000

East Tennessee State University
1276 Gilbreath Dr, Box 70300, Johnson City, TN 37614-1700, 423-439-1000

Lee University
1120 N Ocoee St, Cleveland, TN 37311, 423-614-8000

The University of Tennessee at Chattanooga
615 McCallie Ave, Chattanooga, TN 37403-2598, 423-425-4111

Carson-Newman College
1646 S Russell Ave, Jefferson City, TN 37760, 865-471-2000

King University
1350 King College Rd, Bristol, TN 37620-2699, 866-901-5849

Fisk University
1000 17th Ave N, Nashville, TN 37208-4501, 615-329-85000

Tennessee State University
3500 John Merritt Blvd, Nashville, TN 37209-1561, 615-963-5111

Christian Brothers University
650 E Parkway S, Memphis, TN 38104, 901-321-3000

Tennessee Wesleyan University
204 East College Street, Athens, TN 37303, 423-745-7504

Trevecca Nazarene University
333 Murfreesboro Rd, Nashville, TN 37210, 614-248-1200

Bethel University
325 Cherry Ave, McKenzie, TN 38201, 731-352-4000

Austin Peay State University
601 College St, Clarksville, TN 37044, 931-221-7011 or 877-861-2778

Lincoln Memorial University
6965 Cumberland Gap Pky, Harrogate, TN 37752-9900, 423-869-3611

Free Will Baptist Bible College
3606 West End Ave, Nashville, TN 37205-0117, 615-383-1340

University of Memphis Lambuth
705 Lambuth Boulevard, Jackson, TN 38301, 731-427-4725

Tusculum College
60 Shiloh Road, Greeneville, TN 37743, 423-636-7300

Lane College
545 Lane Ave, Jackson, TN 38301-4598, 731-426-7500

Crichton College
255 N Highland, Memphis, TN 38111-1375, 901-320-9700

Nashville State Technical Community College
120 White Bridge Rd, Nashville, TN 37209-4515, 615-353-3333

Le Moyne-Owen College
807 Walker Ave, Memphis, TN 38126-6595, 901-435-1000

WGU Tennessee
501 Corporate Centre Dr, Suite 390, Franklin, TN 37067, 855-948-8495

This page was intentionally left blank.