



Department of
**Mental Health &
Substance Abuse Services**

Institutional Review Board (IRB) Policies and Procedures

UNDER CONSTRUCTION

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2018 Common Rule Changes

BEGINNING JANUARY 21, 2019, all new research proposals¹ will be reviewed in accordance with 2018 Common Rule requirements. Research under TDMHSAS IRB oversight prior to that date will continue to be reviewed in accordance with pre-2018 Common Rule requirements. Among the 2018 Common Rule changes are the expansion of exemption criteria as well as changes in consent documents. Exemption status of research, however, will continue to be determined by the IRB, so the researcher/investigator should consult with the IRB Administrator regarding any questions related to submission. Researchers/investigators must continue to submit any changes to the IRB for approval. This includes minor changes, such as changes to the principal investigator (PI), as well as major changes to the research. Moreover, researchers/investigators must continue to report adverse events and noncompliance issues such as protocol deviations.

Essentially the 2018 Common Rule offers more options for exemptions while continuing to protect subject/participant privacy and confidentiality. Additionally, Informed consent documents will contain greater detail than previous due to the 2018 Common Rule. The following requirements are valid under the 2018 Common Rule and will be adhered to by the TDMHSAS IRB:

- Exemption status will be determined by the IRB, not the researcher/investigator. At minimum, exempted studies may require limited IRB review, particularly if they contain sensitive and/or identifiable information or biospecimens. Limited IRB review will ensure adequate privacy safeguards and maintenance of confidentiality for participants/service recipients.
 - Research involving deception can be exempt under the 2018 Common Rule if the subjects/participants prospectively agree that they will be unaware of or misled about the nature/purpose of the research.
 - The Subpart B population (i.e., pregnant women, human fetuses, and neonates) is eligible for exempt status under all 2018 Common Rule exemption categories.
 - The 2018 Common Rule requirement is a change from the pre-2018 rule for Subpart C subjects/participants (i.e., prisoners). Exemptions can now apply to research involving a broader subject/participant population if the research only incidentally includes prisoners.

¹ New proposals with funding from the Department of Justice (DOJ) will be reviewed under pre-2018 Common Rule requirements, as is the case involving proposals initially reviewed before January 21, 2019. DOJ has not yet signed onto the 2018 Common Rule. New proposals with funding from the United States Food and Drug Administration (FDA) will be reviewed under FDA regulations,

- Secondary research of information or biospecimens for Subpart C subjects/participants can be exempted under the 2018 Common Rule if that research is not seeking to examine prisoners as a subpopulation.
- The 2018 Common Rule allows subjects/participants to continue in exempt research if they become prisoners during the course of the study.
- Under the 2018 Common Rule, exempt research involving children (i.e., participants covered by Subpart D) may fall into categories 1, 4, 5, 6, 7 or 8. Exemption is not allowable when children are involved if the information/biospecimens include identifiable information that is reviewed under a limited IRB review.
- The 2018 Common Rule does not allow exemption of research involving the public behavior of children if the researcher/investigator participates in the activities being observed. This requirement is consistent with the pre-2018 rule.
- Research in which children participate in surveys or interviews may not be exempt under the 2018 Common Rule, as was the case with the pre-2018 rule.

The 2018 Common Rule requires that consent documents contain information in sufficient detail and presented/organized in such a manner that the participant/subject/service recipient can make his or her own informed decision about whether to participate in the research. Further, consent documents must contain key information in the beginning that identify the purpose, benefits, risks, and alternatives to the research, while helping the prospective participant utilize this information in arriving at an informed decision.

- Researchers/investigators must continue to submit any changes to the research to the IRB for approval. This includes minor changes, such as changes to the principal investigator (PI), as well as major changes to the research.
- Researchers/investigators must continue to report adverse events and noncompliance issues such as protocol deviations.
- Limited IRB review may now be conducted through the exempted and/or expedited review process as deemed necessary.
- The TDMHSAS IRB voted not to approve single IRB review or the use of the broad consent option in consent documents.

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 Officer 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.
- d) The following categories were designated as non-research in the 2018 Common Rule:
 - (1) Journalistic and scholarly activities such as journalism biography, legal research, literary criticism, oral history, and historical scholarship.
 - (2) Public health surveillance activities.
 - (3) Collection and/or analysis of biospecimens, information, or records for criminal investigative purposes or criminal justice.
 - (4) Certain activities in homeland security, defense, intelligence, or other national security missions.
- e) Research activities may include studies involving human participants, records research, specimen research, and research specified in grant proposals.
- f) 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.
- g) The following categories were designated as non-research in the 2018 Common Rule:

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 - (2) Public health surveillance activities.
 - (3) Collection and/or analysis of biospecimens, information, or records for criminal investigative purposes or criminal justice.
 - (4) Certain activities in homeland security, defense, intelligence or other national security missions.
- h) Research activities may include studies involving human participants, records research, specimen research, and research specified in grant proposals.
- i) 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.
- j) The following categories were designated as non-research in the 2018 Common Rule:
- (1) Journalistic and scholarly activities such as journalism biography, legal research, literary criticism, oral history, and historical scholarship.
 - (2) Public health surveillance activities.
 - (3) Collection and/or analysis of biospecimens, information, or records for criminal investigative purposes or criminal justice.
 - (4) Certain activities in homeland security, defense, intelligence, or other national security missions.
2. The IRB will uphold the ethical principles delineated in The Belmont Report. Those principles include:

- a. **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.
 - b. **Beneficence.** This principle emphasizes the dictum of “do no harm” so that expected benefits are maximized and possible risks of harm are minimized.
 - c. **Justice.** This principle focuses on the fairness in which research benefits and burdens are distributed.
3. The TDMHSAS IRB will apply regulations 45 Code of Federal Regulations (CFR) Part 46, Subpart A through E. The subparts deal with the following:
- a. Subpart A – Basic DHHS Policy for Protection of Human Research Subjects (also known as the “Common Rule”).
 - b. Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
 - c. Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
 - d. Subpart D– Additional Protections for Children Involved as Subjects in Research
 - e. Subpart E – Registration of Institutional Review Boards
4. 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.
5. The IRB will apply additional protections where relevant including Tennessee Code Annotated (Tenn. Code. Ann.) Title 33 and 42 CFR Part 2 of the Confidentiality of Alcohol and Drug Abuse Patient Records.

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 Officer 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 review and/or approval are 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.1.2) a-d) of

this document.) Sometimes research may be exempted but still required limited IRB review to ensure privacy and confidentiality considerations.

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 10:00 AM to 11:30 AM central time. However, meeting dates/times may require adjustment to ensure the presence of a quorum. Meetings may be cancelled 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 voting membership, will be 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 will not require a quorum for approval. However, voting will 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.)* Summaries of the disposition of expedited

reviews will be presented at the next full review meeting and/or electronically.

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 PIs/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.

Exemptions might be considered under certain categories and conditions under the 2018 Common Rule. Providing appropriate protections is still critical.

- 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. Also, the 2018 Common Rule creates some latitude for exemptions under specified circumstances.

- 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 into 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 PI/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, protocol deviations, 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 PI/researcher because participants are no longer being enrolled and follow-up and/or data analysis are the only activities being conducted. Close-out requests must include a detailed description of how privacy and confidentiality will be maintained, including final disposition of the data/biospecimens. Continuing review may be the preferred request if such was a required condition of the IRB's review.

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 III.A.4.a. of this document.
5. The IRB will conduct continuing review of research activities, as deemed necessary, involving appropriate studies as delineated in Section III.A.4.b of this document.
6. Limited IRB review will be conducted for exempted and/or expedited research as deemed necessary as discussed in Section III.A.4.c of this document.
7. The IRB will conduct review of amendments to previously approved research as delineated in Section III.A.4.d of this document.
8. The IRB will close-out a study when notified by the Principal Investigator (PI) or his or her designee that the only remaining activities are service recipient/participant follow-up and/or data analyses. Identified and/or de-identified data might be involved.

9. The IRB may take other actions such as suspending research activities when deemed 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. Any renewal or update submitted electronically, and approved by OHRP, starts a new five-year effective period
2. The IRB Administrator (IA) will ensure that all necessary updates, including changes to the membership, are reported to OHRP in a timely manner.
3. The IA 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 IA 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. PIs/researchers should aim to have proposals to the IRB Administrator (IA) within 20 days of the next scheduled IRB meeting.
 - d. Determine if a study or any amendments require full, expedited, or limited IRB 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 required by Federal regulations 45 CFR Part 46.
- f. Receive necessary information required for the IRB to officially closeout 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 thirty (30) days to meet conditional requirements without penalty, unless otherwise indicated. Stamped documents will be provided within ten (10) working days of full approval (i.e., all conditional requirements have been met). Proposal status, including full approval, may be provided electronically and/or in hard-copy format. Notification of approval will also be sent in the form of a letter signed by the TDMHSAS-IRB Chairperson, with copies to the TDMHSAS Commissioner and Deputy Commissioner and/or other appropriate parties.
- l. Notify researchers regarding continuing review, if possible. (NOTE: Researchers are responsible for contacting the IRB Administrator about continuing review, if required, whether or not they receive reminder notification from the IA.)
- 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, including amendments 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 and provide a “30-day grace” period for study expiration under these circumstances.)
2. Proposals, including amendments, 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 format for the proposal is available on the TDMHSAS Web site at https://www.tn.gov/content/dam/tn/mentalhealth/documents/Suggested_IRB_Proposal_Format.pdf. The suggested format is also contained in the Appendices of this manual. The PI/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-format document.
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 TDMHSAS-IRB website, the Collaborative Institutional Training Initiative (CITI), or another 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 UNLESS otherwise designated by the IRB.
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 have access to the service recipients/participants or their personal information 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 to 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 TDMHSAS-IRB website, the Collaborative Institutional Training Initiative (CITI), or another reputable training entity, preferably at the time the research proposal is submitted for review, but certainly in advance of receiving notification of full approval. Exceptions include when the key study personnel have a **valid** training certificate on file with the TDMHSAS IRB through a previously reviewed study/amendment. **Valid** is defined as within three (3) years from the date on the certificate UNLESS otherwise designated by the IRB.
8. PIs can submit amendments to currently approved research at any time. Depending on the 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. Under the 2018 Common Rule, close-out requests may be submitted when remaining activities only involve follow-up and/or data analysis. Data can be identified or de-identified. (Pre-2018 studies and DOJ or FDA studies must adhere to pre-2018 requirements for closeout. These requirements included no more enrollment or follow-up of participants and, if there were data analysis, the analyses would only involve de-identified data.) All close-out requests should further include information about data storage, retention, and usage. In addition, the data can only be used for academic or professional purposes, not for personal or financial gain. Any new use of service recipient/participant's data will require additional consenting because the TDMHSAS IRB does not honor the use of broad consent at the time of this writing.
10. All 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 information (data and/or biospecimens) 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 reasonable and/or necessary, PIs/researchers should notify service recipients/participants that the research study is closing out.

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.

A. 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/or approved by the TDMHSAS IRB. **PROGRAM EVALUATION ACTIVITIES MAY 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 TDMHSAS service recipients/participants, their records, or biological specimen.
 - 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 may need to be an IRB requirement as part of the evaluation activities, despite all activities involving human subjects being carried out by a subcontractor or collaborator.
3. IRB review and/or approval will also be required when data originally collected for non-research purposes will be used in research.

Sometimes information (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. Per the 2018 Common Rule, secondary research may include information and/or biospecimens that were not in existence at the start of the research but will be collected for clinical purposes in the future. If collected data were not identifiable, efforts cannot be undertaken to identify them. At the very least, the IRB may perform limited review. It will be up to the IRB to determine whether the after-the-fact submission will be accepted. The IRB may refuse to review the proposal, especially if there are indications that avoiding the IRB was the reason a proposal was not submitted early during project implementation.

4. The TDMHSAS IRB will conduct initial, limited, and continuing reviews, as deemed appropriate, in addition to reviewing amendments for currently reviewed and/or approved research.
 - a. *Initial Review (Assumes exemption has been ruled out or that limited review was deemed necessary.)*
 - 1) Initial review encompasses the first full 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), Title 33, and 42 CFR Part 2 where applicable.

- 3) Requests to conduct research requiring initial review must be in writing and include a cover letter addressed to the TDMHSAS-IRB Chairperson.
- 4) An adequate description of the study should be submitted despite the fact that the study may be exempted. The IRB needs to have a “full picture” of the study.
- 5) 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 ethics² including informed consent procedures and forms that comply with 45 CFR §§ 46.116-117, as well as how the data will be collected and protected; and
 - g) Data analysis.
- 6) 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

² 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

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). PIs/researchers can decide if they will consent these individuals as youth or adults. 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) Discussion of any foreseeable risks or discomforts to the subject.
- c) Discussion of any benefits to the service recipient/participant.
- d) Disclosure of any alternative treatments that might be advantageous to the participant.
- e) Statement indicating the extent to which confidentiality of the data will be maintained.
- f) 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.
- g) Explanation of whom to contact for further information.
- h) 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.
- i) New requirements as delineated under the 2018 Common Rule at 46 C.F.R. § 46.116-117.

- 7) The 2018 Common Rule makes Waiver of Consent/Authorization for identifiable biospecimens a rare event, especially when identifiable private information or specimens are involved. The TDMHSAS IRB voted not to allow the broad consent option for researchers in consent documents so any Waiver of Consent/Authorization request requires the PI/researcher to demonstrate to the IRB that the:
- a) Research involves no more than minimal risk to participants;
 - b) Research cannot practicably be carried out without using the identifiable information/specimens;
 - c) Waiver does not adversely affect the welfare and/or rights of participants; and
 - d) Participant and/or his or her legally authorized representative is offered pertinent information regarding the study when completed, if appropriate.

- 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/Deputy 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. The TDMHSAS IRB voted not to approve the single IRB review option offered through the revised 2018 Common Rule.

- b. Continuing Review (Required of studies reviewed under the pre-2018 Common Rule or deemed necessary at initial, limited, and/or subsequent reviews under the revised 2018 Common Rule.)

- 1) Proposals requiring continuing review have been previously

reviewed and approved by the TDMHSAS IRB under the pre-2018 Common Rule or the IRB requires routine follow-up of privacy and confidentiality protections under the new 2018 rule. In most cases, service recipient/participant enrollment will be ongoing at the time of the continuing review.

2) Continuing review may also involve:

- a) Exempted research where routine follow-up of privacy and confidentiality protections was required by the IRB; and/or
- b) Studies reviewed and approved in advance of January 21, 2019, where annual continuing review was the standard.

3) Continuing review will be conducted at intervals appropriate to the degree of risk. The TDMHSAS will determine intervals based on a study-by-study basis.

c. *Limited IRB Review (Related to concerns regarding privacy and/or confidentiality for specified research categories that have been exempted per the revised 2018 Common Rule.)*

- 1) Required under the new 2018 Common Rule and aims to provide adequate provisions for protecting the privacy of the service recipients/participants and maintaining the confidentiality of the information collected for the study.
- 2) For this option, collected information (data and/or biospecimens) tends to be identifiable and/or sensitive, though risk is minimal.
- 3) The 2018 regulations indicate that limited IRB review be expedited, i.e., conducted by either the chairperson or an experienced IRB member. However, OHRP identifies the 2018 requirements as the "floor". **The TDMHSAS IRB will determine responsibility for limited IRB review.** Limited IRB review will be a function of the nature of the study and adequate protections as perceived by the TDMHSAS-IRB membership. Ongoing review (i.e., the equivalence of continuing review) to ensure adequate privacy and confidentiality provisions may be recommended by the membership.

- d. Review of Amendments to Currently Approved Research (*Includes research obtaining Initial, Limited, or Continuing review.*)
- 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) Formal submission is required for amendments, major or minor. The cover letter should indicate which components are being amended and why. Amendments requiring changes to the protocol or forms should be so documented; use "Track Changes".
 - 3) Level of risk and/or other factors associated with the changes will determine whether the amendment request will be expedited or handled at a convened meeting. Changes in PI will likely be expedited. More substantial changes, especially changes that may impact risk level, will likely be handled at a convened meeting.
 - 4) An amendment(s) cannot be implemented until IRB approval (expedited or full review) has been rendered.
 - 5) Review dates and/or version/revision numbers on stamped documents for amendments will change. However, the oversight expiration date will remain unchanged unless the amendment review is part of a scheduled continuing review.

B. Review Process.

1. Initial review, continuing review, limited 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

or services recipients at the RMHIs regardless the level of risk, will be conducted at a full Board (convened) meeting.

3. Expedited reviews will be restricted to minimal risk studies and to review of amendments requiring minor changes and no increase in risk level. Some studies that could undergo expedited review, however, may be reviewed during a full Board (convened) meeting.
4. Full Review (i.e., full Board meeting)
 - a. The types of research which may 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 voting 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 (convened) 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 a small part of the proposal discussion will abstain from voting.
 - 3) Members will vote to approve, approve with conditions, disapprove, table (postpone), closeout, 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 the Board's 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-to-two 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 noninvasive means;
 - 4) Routine, noninvasive 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. An IRB may also use the expedited review for research for which limited IRB review is a condition of exemption under 45 CFR § 46.104(d)(2), (3), (7), and (8).
 - e. 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).
 - f. Expedited review will follow the same process and time frame as full review.
 - g. If review warrants a Waiver of Consent/Authorization, the waiver form and accompanying PI Assurance Form must be completed.
 - h. 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 includes research as described in 45 CFR § 46.104.

C. 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 or that limited review was deemed necessary.)

- 1) Instructions for submitting initial review requests to conduct research (proposals) are available on the TDMHSAS-IRB Web page:
https://www.tn.gov/content/dam/tn/mentalhealth/documents/IRB_Proposal_Instructions%20Update%2001.21.19%20DRAFT.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 https://www.tn.gov/content/dam/tn/mentalhealth/documents/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 or

that this requirement was dictated by limited IRB review results.)

- 1) Instructions for submitting continuing review requests (proposals) are available on the TDMHSAS-IRB Web page: https://www.tn.gov/content/dam/tn/mentalhealth/document/s/IRB_Proposal_Instructions%20Update%2001.21.19%20DRAFT.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 review processes and time frames.
- c. Review of Currently Approved Research by Amendment *(Includes research obtaining Initial, Limited, or Continuing review)*
- 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 or that limited review was deemed necessary.)*
 - 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 (*Required of studies reviewed under the pre-2018 Common Rule or deemed necessary at initial, limited, and/or subsequent reviews under the revised 2018 Common Rule.*)
- 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 *(Includes research obtaining Initial, Limited, or Continuing review)*
 - 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 upon initial review. (Continuing review beyond one year may not be deemed necessary, especially in light of the new 2018 Common Rule with its option to eliminate continuing review.) 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 participants 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.
 - 1) This allegation may be brought directly by the PI/other researchers, as well as other sources.
- c. A discovery by the PI of potential additional risks.
- d. IRB deliberations.

Often noncompliance will take the form of protocol deviations. These deviations are unplanned diversions from the protocol that was not intended to be nor implemented as systematic change. The three (3) types of protocol deviations are: those that occur because a researcher/investigator intentionally decides to deviate from the approved protocol; those identified before they occur but cannot be prevented; and those that are discovered after they happen. Any such deviation should be reviewed and approved by the IRB and/or other necessary entities in advance of implementation. Intervention drift as evident in protocol deviations is indicative of noncompliance.

2. The IRB will notify 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 maybe 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.

The action mentioned in #4 will likely be undertaken when a PI discovers and/or brings forth an allegation of noncompliance that falls into the protocol deviation category in lieu of being placed on Administrative Hold. In some cases the PI/researcher will recommend a course of action that is approved by the Chairperson, his/her designee, and/or the IRB. This recommendation may be accepted in full, be expanded and accepted, or totally replaced with a new recommendation from the Chairperson, his/her

designee, and/or the IRB.

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 new 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.

A. 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.

B. 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.

C. 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.

D. 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.

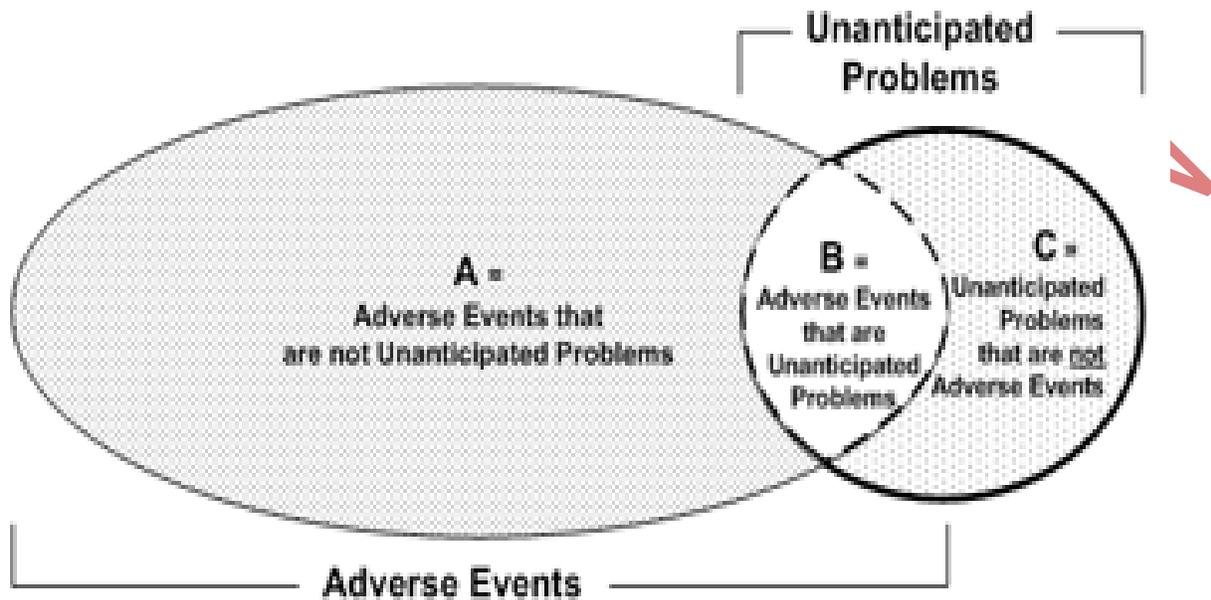
VII. Policy on Reporting Unanticipated Problems and Adverse Events Involving Risk to Service Recipients/Participants or Other Entities

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 CFR Part 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 types 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.

UNDER CONSTRUCTION

REFERENCES

UNDER CONSTRUCTION

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UNDER CONSTRUCTION

GLOSSARY

UNDER CONSTRUCTION

Definitions

- **Broad Consent.** Such consent allows for consent of an unspecified range of future research subject to a few content and/or process restrictions. However, TDMHSAS IRB does not allow for broad consent at this time.
- **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.** Includes both physical procedures by which data information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - Interventions are considered "*benign behavioral interventions*" when they are painless, harmless, not physically invasive, brief in duration, not likely to have a significant adverse lasting impact on the subject/participant, and there is no reason for the researcher/investigator to think that the participants/service recipients will find the intervention(s) embarrassing or offensive.
- **Minimal Risk.** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- **Non-identifiable Data.** See De-identified Data above.
- **Participant.** A human subject who consents to participate in a research activity. **Per 2018 requirements,** “human subject” also includes collection of identified biospecimens. This individual or biospeciman may also be referred to as a “service recipient” or “subject”.
- **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.
- **Prospective agreement.** The subject/participant is asked to participate in a benign, behavioral intervention and orally expressed his or her agreement.
- **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.
- **Protocol deviation.** A typical kind of noncompliance that may occur as one of the following:
 - Protocol deviation that is discovered after it occurs.
 - Protocol deviation identified before it occurs, but cannot be prevented.
 - Deviation that occurs because the researcher/investigator or other party involved in conducting the research intentionally decides to deviate from the approved protocol.
- **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. A service recipient may also be referred to as a subject or a participant within this document.
- **Subject.** A term used interchangeably within this document with “participant” and “service recipient”.

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APPENDICES

UNDER CONSTRUCTION

APPENDIX A

Suggested Research Proposal Format Document

UNDER CONSTRUCTION

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):	<input type="checkbox"/> M.D. <input type="checkbox"/> Ph.D. <input type="checkbox"/> M.S. <input type="checkbox"/> B.S. <input type="checkbox"/> Other, specify:
Job Title:	
Affiliation:	
Human Subjects Training Completed:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Mailing Address:	
Phone:	
Fax:	
E-mail:	

<Co-Principal Investigator or Evaluator>

Name:	
Degree(s):	<input type="checkbox"/> M.D. <input type="checkbox"/> Ph.D. <input type="checkbox"/> M.S. <input type="checkbox"/> B.S. <input type="checkbox"/> Other, specify:
Job Title:	
Affiliation:	
Human Subjects Training Completed:	<input type="checkbox"/> Yes <input type="checkbox"/> 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:		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Name: Affiliation: Phone: Email:		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Name: Affiliation: Phone: Email:		<input type="checkbox"/> Yes <input type="checkbox"/> 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:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Name: Affiliation: Phone: Email:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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:	<input type="checkbox"/> Full <input type="checkbox"/> Expedited <input type="checkbox"/> Exempt
Review Date:	___/___/20__
Decision:	<input type="checkbox"/> Approved <input type="checkbox"/> Approved with conditions <input type="checkbox"/> Not approved/re-submit
IRB Administrator Initials: _____	

APPENDIX B

Unanticipated Problem/Adverse Event Report Form

UNDER CONSTRUCTION

*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.

*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

*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>.

echappell/TDMHS-ASResearchTeam

Created: 12/21/2012

Revised: n/a

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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 Chair/Designee
echappell/TDMHSAS IRB

Created: 01/20/2014

Date

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. (If **NA**, initial here ____.)
2. I verify that protected health information (PHI) collected for this study will be protected from improper disclosure and use. (If **NA**, initial here ____.)
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. (If **NA**, initial here ____.)
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. (If **NA**, initial here ____.)
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. (If **NA**, initial here ____.)

Signature of Principal Investigator

Date

Signature of TDMHSAS IRB Chairperson/Designee

Date

APPENDIX E

Document Translation Requirements

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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.

To assist researchers in meeting this requirement, the TDMHSAS IRB has identified a sample of translation services in East, Middle, and West Tennessee. 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 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

Tennessee Colleges and Universities Contact Information

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

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