HOW TO SUBMIT A RESEARCH PROPOSAL

SPECIFIC REQUIREMENTS FOR INITIAL REVIEW SUBMISSION

When Do I Need To Submit A Proposal To The IRB?

Researchers/investigators must submit proposals according to the submission schedule indicated on the Webpage, in these instructions, and in the Policy and Procedures Manual. All proposals should include a cover letter addressed to Dr. Terry Holmes, Chairperson of the Tennessee Department of Mental Health and Substance Abuse Services Institutional Review Board (TDMHSAS IRB). The study being conducted might require:

- Data collection from patients/service recipients;
- The use of patient/service recipient records (including criminal records) from any Regional Mental Health Institute (RMHI) or programs directly managed by Central Office; OR
- Collection and/or analysis of biospecimens, including but not limited to blood, urine, and cheek swabs, at any Regional Mental Health Institute (RMHI) or programs directly managed by Central Office.

BEGINNING JANUARY 21, 2019, all new research proposals 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 elements 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.

What Needs To Be Included In The Proposal?

The TDMHSAS IRB has provided a sample format for suggested use when submitting a proposal.

The proposal should be concise and include the following:

1. Study title
2. Study purpose
3. Research objectives, questions, or hypotheses
4. Research design including information on the target population
5. Policies and procedures for data storage and security
6. Research method(s) including instrumentation (commercial or locally developed)
7. Research ethics with specific information regarding the protection of privacy and maintenance of confidentiality for patients/service recipients. Informed-consent procedures and forms should be

included.

8. Data analysis

The TDMHSAS IRB highly values data security, and IRB proposals must include a strategy for data governance, explaining which data governance regulations researchers/investigators will be following in order to protect patient/service recipient information. This IRB will also evaluate proposals for compliance with 42 CFR Part 2 as appropriate.

Research ethics should specifically incorporate how the researcher(s)/investigator(s) will obtain informed consent and protect the privacy and confidentiality of participants throughout the study. A copy of all informed-consent forms for study participants, as well as any other pertinent forms and assessment tools, must be submitted at the time of the request. Per 2018 Common Rule requirements, consent documents must contain certain elements. *We have included a sample consent template from the University of California, Davis campus, on our Webpage to help researchers/investigators include all necessary elements going forward.* Also keep in mind that informed consent documents must be written in patient/service recipient-friendly language, with the lowest appropriate reading level utilized (i.e., not higher than 6th grade reading level to the extent possible). Consent documents must inform patients/service recipients regarding who will have access to their information/biospecimens and how their information or biospecimens will be used. Researchers/investigators cannot ask for broad consent of patient/service recipient data at this time (i.e., requests to use identifiable patient/service recipient information/biospecimens in the future for purposes that may not yet be known).

What Additional Materials Besides My Proposal Must I Provide?

- ***When conducting research on programs that you as researcher/investigator are not directly connected, are outside of your responsibilities as a TDMHSAS/contracted-agency employee, or requesting data from the RMHIs***, the proposal must be accompanied by written executive approval from the agency or institution where the research will be conducted. The executive approval letter must contain one or more of the following:
    - A statement about previous IRB review if conducted prior to submission to the TDMHSAS IRB. *If no previous IRB review was conducted*, this must be clearly indicated and an explanation provided.
    - A statement concerning approval or exemption of the proposed research by the agency IRB, institution IRB, or other appropriate IRB. *If exempted*, include a statement that thoroughly explains the nature of the exemption.
    - Evidence of support from TDMHSAS Commissioner or designee, Chief Executive Officer of an RMHI or designee, and/or TDMHSAS Central Office staff managing the project where the research will be conducted.

The TDMHSAS IRB does not allow single IRB review at this time. Per 2018 requirements, our IRB has until January 20, 2020 to consider that option. This document will be appropriately updated once a decision has been reached regarding this option.

- Documentation of successful human subjects' protection training must be met by the researcher, Principal Investigator, and/or any persons charged with data collection or analysis, particularly identifiable information/biospecimens. Further, this documentation serves as one condition of approval by the TDMHSAS IRB. Human subjects' protection training may be obtained through the TDMHSAS IRB, the Collaborative Institutional Training Initiative (CITI), or any other reputable training program approved by the TDMHSAS IRB.
    - The TDMHSAS IRB provides a link on the Webpage to its free human subjects' protection

training. This training replaces the free training formerly offered by the National Institutes of Health (NIH).

- Researchers affiliated with a fairly active research institution of higher education likely have access to CITI training. The CITI Program provides research ethics education to all members of the research community but a subscription is required.

- A cover letter addressed to the TDMHSAS-IRB chairperson must be included with the proposal.
- Researchers/investigators must further delineate and provide documentation of specific activities to be carried out by TDMHSAS staff, if any, in addition to research activities of study staff.
- Per 2018 Common Rule requirements, waivers of consent/authorization may be available for certain studies of minimal risk. However, waiver approval will be an IRB decision. Researchers/investigators will be required to demonstrate that the research could not practicably be carried out without using patient/service recipient information in an identifiable format. Thus, researchers/investigators will need to describe in detail why they cannot use de-identified data/biospecimens for their research. The TDMHSAS IRB will now conduct a limited IRB review, at the very least, to ensure that procedures/mechanisms for protecting privacy and maintaining confidentiality of patients/service recipients are acceptable. Any waivers of consent/authorizations, if issued, will specify that limited IRB review has also been conducted.

What Else Should I Know About the TDMHSAS IRB?

- The TDMHSAS IRB is approved by and registered with the U.S. Department of Health & Human Services (HHS), Office for Human Research Protections (OHRP).
  - The TDMHSAS IRB makes decisions in accordance with the three basic ethical principles outlined in The Belmont Report.
  - Further, the IRB adheres to the specific protections of human study subjects as promulgated in the HHS Code of Federal Regulations (CFR) Title 45: Public Welfare, Part 46: Protection of Human Subjects as well as 42 CFR Part 2.
- Research approved on or after January 21, 2019 will comply with the 2018 Common Rule and as chosen to be implemented by the TDMHSAS IRB. Studies approved prior to the aforementioned date will continue to be reviewed under the pre-2018 Common Rule.

Address proposal cover letter to:

TDMHSAS Institutional Review Board
Terry Holmes, M.D., M.P.H. & T.M.
IRB Chairperson
Division of Clinical Leadership
6th Floor, Andrew Jackson Building
500 Deaderick Street
Nashville, TN 37243
Terry.Holmes@tn.gov

Send proposal materials to:

TDMHSAS IRB
Edwina Chappell, Ph.D.
IRB Administrator
Division of Clinical Leadership
6th Floor, Andrew Jackson Building
500 Deaderick Street
Nashville, TN 37243
Edwina.Chappell@tn.gov

- If you have any questions, call Dr. Chappell at 615-741-9476 or email Edwina.Chappell@tn.gov.
- Decisions regarding proposals, including requests for additional information, will be provided within ten (10) working days from the date that the proposal is reviewed.
- The TDMHSAS IRB is scheduled to meet the third Friday of each month. However, the Chairperson has authority to call meetings and recommend other appropriate methods of review. Moreover, monthly IRB meetings can be scheduled to other days during a month.
- Proposal materials may be sent electronically.
- **Please include an email address and/or other appropriate contact information with all requests and proposals.**

SPECIFIC REQUIREMENTS FOR CONTINUING REVIEW SUBMISSION

The TDMHSAS IRB retains authority to call for continuing review of any research initially brought before this board. Any changes to the research proposal may be cause for continuing review of the research. As per 2018 Common Rule requirements, requests for continuing review will no longer be necessary when the only remaining research activity is data collection or data analysis. Such review may also not be necessary if limited IRB review is conducted initially***. The IRB will specify and document whether continuing review will be necessary as part of initial approval***. If required:

- Please provide, at minimum, the following materials with your request for continuing review:
    1. Cover letter to the TDMHSAS-IRB chairperson requesting the continuation of review. Include information regarding changes in this letter to facilitate review.
    2. Summary of the current research
        a. Brief overview of the project
        b. Research question(s)
        c. Preliminary data
            i. Demographics
            ii. Successes/Challenges
            iii. Outcome data, if available
    3. Copies of forms, questionnaires, or other documents, especially those requiring an IRB stamp (e.g., informed consent forms, fidelity scales, adverse event form) if changes to those documents will be necessary. Make sure that any changes being proposed to the documents are shown and submit the document(s) including proposed changes along with the "clean" (unmarked/untracked) document(s)
    4. Any adverse events and/or unanticipated problems.
    5. Any documents related to research activities that have not been reviewed by the IRB since the last review or amendment.
    6. Documentation of investigator training in human-subject protections, if there are changes or a need for updates.

SUBMISSION SCHEDULE

- The TDMHSAS IRB meets the third Friday of each month. However, the chairperson has the authority to convene meetings as necessary. It is also possible that meeting dates within a month may change.
- Researchers submitting proposals for continuing review must submit before the end of the approval time period to avoid suspension of research activities.
- Proposals submitted for review must be received within twenty (20) days of scheduled TDMHSAS-IRB meetings.
- Proposals received outside the window of scheduled meeting dates should allow at least thirty (30) days for review.
- Decisions regarding proposals (including requests for additional information) will be provided within ten (10) working days.
- **Please include an email address and/or other appropriate contact information** in all requests to facilitate communication regarding additional information or decisions that have been made.

REQUIREMENTS FOR OTHER TYPES OF SUBMISSION

- An amendment request might be submitted when there have been changes in study personnel or when the researcher wants to enhance research requirements for the study.
- Closure requests should occur when only data collection or data analysis will be conducted. (For studies under 2018 Common Rule requirements.) Review the Policy and Procedures Manual for specifics regarding this request.
- In every case, **the researcher must submit a cover letter addressed to the TDMHSAS IRB chairperson that details the amendment or closure request**.

CURRENT TDMHSAS-IRB MEMBERSHIP (as of 1/18/2019)

- **Terry Holmes, M.D., M.P.H. & T.M.**
  IRB Chairperson and Chief Medical Officer, Division of Clinical Leadership (DCL), TDMHSAS
- **Wesley Geminn, Pharm.D.**
  IRB Co-Chairperson, Chief Pharmacist, Division of Clinical Leadership (DCL), TDMHSAS
- **Edwina Chappell, Ph.D.**
  IRB Administrator, Licensed Psychologist, Division of Clinical Leadership (DCL), TDMHSAS
- **Bev Fulkerson, M.A.** (alternate member)
  Deputy Assistant Commissioner, Division of Substance Abuse Services (DSAS), TDMHSAS
- **Leandra Mitchell, Esq.** (nonvoting member)
  Special Counsel, Office of General Counsel (OGC), TDMHSAS
- **Ellen Omohundro, Ph.D.**
  Director, Office of Research, TDMHSAS

- **Lydia Haren, M.D.**
  Medical Director, Moccasin Bend Mental Health Institute (MBMHI), TDMHSAS

- **Elizabeth Reeve, J.D.**
  Director, Juvenile Justice Programming, Division of Mental Health Services (DMHS), TDMHSAS

- **Taryn Sloss, B.S.**
  Assistant Commissioner, Division of Substance Abuse Services (DSAS), TDMHSAS

- **Mary-Linden Salter, M.S.S.W.**
  Executive Director, Tennessee Association of Alcohol, Drug, and Other Addiction Substances (TAADAS)

- **Erica Schlesinger, Pharm.D.**
  Assistant Chief Pharmacist, Division of Clinical Leadership (DCL), TDMHSAS

- **Ellyn Wilbur, M.P.A.**
  Executive Director, Tennessee Association of Mental Health Organizations (TAMHO)