

HOW TO SUBMIT A RESEARCH PROPOSAL FOR INITIAL REVIEW

A researcher must submit a proposal to Dr. Howard Burley, Chairperson of the Tennessee Department of Mental Health and Substance Abuse Services Institutional Review Board (TDMHSAS IRB), study being conducted requires:

- data collection from service recipients, or
- the use of patient records from any Regional Mental Health Institute (RMHI) or programs directly managed by Central Office

The proposal should be concise and include the following:

1. Study title
2. Study purpose
3. Research questions or hypotheses
4. Research design including information on the target population
5. Research method(s) including instrumentation (commercial or locally developed)
6. Research ethics* including informed-consent procedures and forms
7. Data analysis

*Research ethics should specifically incorporate how the researcher(s) will obtain informed consent and protect the confidentiality of participants throughout the study. 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.

View a suggested proposal format.

The proposal must be accompanied by written executive approval from the agency or institution where 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 responsible for the project requesting to conduct research.
Project requirements and the agency/institution where the study will be conducted dictate the appropriate person to provide evidence of support for the research.

TDMHSAS IRB is approved and managed by the U.S. Department of Health & Human Services (HHS), Office for Human Research Protections (OHRP).

IRB makes decisions in accordance with the three basic ethical principles outlined in [The Belmont Report](#).

Further, 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](#).

Moreover, IRB ensures that investigators understand and act in accordance with the requirements of HHS regulations for the protection of human subjects when carrying out HHS-conducted or -supported human-subject research. **Therefore, principal investigators submitting proposals must successfully complete and provide documentation of human subjects' protection training as a condition of study approval in addition to the aforementioned required materials.**

Human subjects' protection training may be obtained through the Collaborative Institutional Training Initiative (CITI), National Institutes of Health (NIH), Health Resources and Services Administration (HRSA), or any other reputable training program.

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.

NIH offers *no-cost* [human subjects' protection training](#).

The [HRSA training](#) is also very comprehensive and *free of charge*. Documentation of successful human subjects' protection training must be met and submitted as a condition of approval by the TDMHSAS IRB.

Further delineate specific activities to be carried out by TDMHSAS staff, if any, and the researcher(s)/study staff as part of the study. Waivers of Consent/Authorization are available for certain studies of minimal risk. However, waiver approval is an IRB decision.

A cover letter must be included with the proposal.

Address proposal cover letter to:

TDMHSAS Institutional Review Board
Howard L. Burley, M.D.
IRB Chairperson
Division of Clinical Leadership
6th Floor, Andrew Jackson Building
500 Deaderick Street
Nashville, TN 37243

Send proposal materials to:

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

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) days from the date that the proposal is reviewed.

TDMHSAS IRB meets the third Thursday of each month. However, the Chairperson has authority to call meetings and recommend other appropriate methods of review.

Please include an email address in all requests and proposals.

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SPECIFIC REQUIREMENTS FOR CONTINUING REVIEW SUBMISSION

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
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 that are still being used, especially those that require an IRB stamp (e.g., informed consent forms, fidelity scales, adverse event form). Make sure that any changes being proposed to the documents are listed and submit the document(s) including proposed changes.
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 necessary

SUBMISSION SCHEDULE

The TDMHSAS IRB meets every third Friday of each month in 2016. However, the chairperson has the authority to convene meetings as necessary.

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 if necessary.

Please include an email address 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 typically occur when enrollment has ceased and only de-identified data are being used for data analyses/publications. In the event there is a sponsor, approval to request study closure must be obtained from the former and submitted with the closure request.

Researchers must close out their studies once data collection or analysis of raw, personal data is complete, or if there are other reasons they need to terminate the study.

In every case, **the researcher must submit a cover letter addressed to the TDMHSAS IRB chairperson which details the amendment or closure request.**

CURRENT TDMHSAS-IRB MEMBERSHIP

- **Howard L. Burley, Jr., M.D.**
IRB Chairperson, Chief Medical Director, 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

- **Kurt Hippel, Esq.**
Director, Office of Legislation and Rules, Division of General Counsel (DGC), TDMHSAS
- **Karen Edwards, Ph.D.**
Director, Office of Research, Division of Planning, Research & Forensics (DPRF),
TDMHSAS
- **Terry Holmes, M.D.**
Medical Director, Moccasin Bend Mental Health Institute (MBMHI), TDMHSAS
- **Taryn Sloss, B.S.**
Director, Program Development, 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)
- **Ellyn Wilbur, M.P.A.**
Executive Director, Tennessee Association of Mental Health Organizations (TAMHO)