HOW TO SUBMIT A RESEARCH PROPOSAL FOR INITIAL REVIEW

Effective JANUARY 21, 2019, all new research proposals are being reviewed in accordance with 2018 Common Rule requirements.

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), when the study being conducted requires:

- data collection from service recipients, including employees, or
- the use of patient data/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. Study personnel
4. Research questions or hypotheses
5. Research design including information on the target population
6. Research method(s) including instrumentation (commercial or locally developed)
7. Research ethics* including informed-consent procedures and forms
8. 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. The 2018 Common Rule requires that consent documents contain information in sufficient detail and presented/organized in such a manner that the participant/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. Sample Informed Consent Templates, developed by the University of California (UC), Davis Campus, Office of Research, to help researchers/investigators include the new elements required by the 2018 Common Rule are available on the Webpage and used with permission of the aforementioned UC-Davis, Office of Research.

View the suggested proposal format and submit in desired format with all required components.

If the research requests use of data/biospecimen of TDMHSAS service recipients/employees, the proposal must be accompanied by written executive approval to conduct the research.

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 including the type of data/records that is being requested will dictate the appropriate person to provide evidence of support for the research.

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 research participants as promulgated in the HHS Code of Federal Regulations (CFR) Title 45: Public Welfare, Part 46: Protection of Human Subjects. 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, as well as the Tennessee Code Annotated (Tenn. Code. Ann.) Title 33 and 42 CFR Part 2 of the Confidentiality of Alcohol and Drug Abuse Patient Records.

Moreover, the 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 research participants' protection training as a condition of study approval in addition to the aforementioned required materials. Documentation must further be provided for all identified study personnel.**

The department makes free Human Research Participants' Protections Training available to all potential researchers/ study personnel. This training can be found at https://www.proprofs.com/training/course/?title=tdmhsas-human-research-participants-protections-training_5c7caec1cb5e2. **Human research participants' protection training** may also be obtained through the Collaborative Institutional Training Initiative (CITI) or 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.

Documentation of successful human research participants' 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.

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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
Howard.Burley@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 615-310-9598, 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 second Friday 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.

SPECIFIC REQUIREMENTS FOR CONTINUING/CHECK-IN REVIEW SUBMISSION

Please provide, at minimum, the following materials with your request for continuing/check-in review:

1. Cover letter to the TDMHSAS-IRB chairperson requesting the continuation/check-in 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-research participants' protections, if necessary

SUBMISSION SCHEDULE

The TDMHSAS IRB meets the second Friday of each month. 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. In some cases, e.g., substantial difficulty recruiting participants to the research, researchers may request to terminate the study rather than closing out the study.

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

- **Howard L. Burley, M.D.**
  IRB Chairperson and Chief Medical Officer, Division of Clinical Leadership (DCL), TDMHSAS

- **Wesley Geminn, Pharm.D.**
  IRB Co-Chairperson, Chief Pharmacist and State Opioid Treatment Authority (SOTA), Division of Clinical Leadership (DCL), TDMHSAS

- **Edwina Chappell, Ph.D.**
  IRB Administrator, Licensed Psychologist, Division of Clinical Leadership (DCL), TDMHSAS

- **Sam Boukli, Esq.** (nonvoting member)
  Assistant Deputy Counsel, Division of General Counsel (DGC), TDMHSAS

- **Ellen Omohundro, Ph.D.**
  Director, Office of Research, Division of Research, Planning, Policy, & Legislation (DRPPL), TDMHSAS

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

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

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

- **Bev Fulkerson, M.A.**

Deputy Assistant Commissioner, Division of Substance Abuse Services (DSAS), TDMHSAS

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

CURRENT TDMHSAS-IRB ALTERNATE MEMBERS

- **Zack Blair, B.S.**
  Director of Legislation and Rules, Division of Research, Planning, Policy, & Legislation (DRPPL), TDMHSAS

- **Current Pharmacy Resident, Pharm.D.**
  Pharmacy Resident, Division of Clinical Leadership (DCL), TDMHSAS