



UNIVERSITY OF MINNESOTA
Driven to DiscoverSM

Need to Know

- ETHOS launches on March 27, 2017.
- When ETHOS launches, all new studies must be submitted via ETHOS.
- All current applications and appendices will be retired.
- A protocol will be required for ALL studies.
- IRB approved protocol templates are available for use now.
- Determination form will be replaced with project template.
- Advisors will have to submit the IRB SmartForm for student-researchers

Need to Know

- Use of other protocol templates is allowed but investigators must review guidance to determine if additional, supplemental information will be required.
- An active UMN internet ID is required to access

Need to Know

- Studies and submissions in the review process or approved prior to March 27 will remain outside of ETHOS until data conversion. Investigators will continue to use the existing change in protocol form, report form and continuing review process until data conversion.
- Studies will be migrated in three phases:
 - Student led social/behavioral research 5/20
 - Faculty led social/behavioral research 7/15
 - Medical research 9/9
- Exempt studies will not be migrated.

Need to Know

- Courseroom exercises IRB requirement retired

Research projects that occur within courses are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques as well as data analysis. Typically such projects are quite limited in scope and are not intended for dissemination or to contribute to generalizable knowledge.

Course-based research projects and data collection activities may be exempt from IRB review. Such projects:

- should not include sensitive or personal information or otherwise put participants at risk; and
- the data must be recorded anonymously (i.e., with no name, social security number, or any other code that can be linked to a participant).

These **projects are considered "courseroom exercises"** and are not subject to review by the IRB unless the student-researcher anticipates using the results in his or her dissertation, publishing the results or presenting at a professional meeting, or unless the faculty expects to compile all students' results with the intention of publishing or presenting. In those situations, the IRB will make a determination regarding oversight requirements, if any.

Apply to IRB

The University of Minnesota IRB is committed to the protection of human participants in research. The following outlines the process for submitting applications and other information to the IRB for review and approval.

ETHOS

Learn about ETHOS (Ethical Oversight Submission System), the University's new, [web-based platform for IRB submissions](#). Starting March 27, 2017, all new studies will be submitted through ETHOS.

New studies

Learn how to submit an application for a [new study](#) to the IRB for review and approval. Includes information about submission requirements and the review process.

Modifications to approved studies

Need help?

Email or call the IRB:

irb@umn.edu

(612) 626-5654

[Staff directory](#)

Office Hours: 8 - 4:30

Office Location:

D528 Mayo Memorial Bldg

Mailing Address:

MMC 820

420 Delaware St. SE

Minneapolis, MN 55455

New Resources

[ETHOS Training Page](#)

New IRB submission checklist

The IRB has released the [New Study Submission Checklist](#) to help researchers and research staff identify the documents and information needed to submit a new study. This checklist reflects the new study submission process in ETHOS.

IRB Process - Resources

New studies

Learn how to submit an application for a [new study](#) to the IRB for review and approval. Includes information about submission requirements and the review process.

Modifications to approved studies

Learn how to [submit changes](#) to the IRB for approved studies. Includes information about types of changes and the potential outcomes of IRB review.

Continuing review

Learn how to submit to the IRB for [continuing review](#). Includes information about submission requirements.

Reportable new information

Learn how to [submit reports](#) to the IRB, including but not limited to protocol violations, unanticipated or anticipated problems, monitoring reports, and sponsor or agency reports, suspensions and/or terminations. Includes information about submission requirements, the review process, reporting requirements to institutional authorities and agencies, and review outcomes.

Study closure

Learn how to [close or inactivate an approved study](#) with the IRB. Includes information on when a study may be inactivated or closed and submission requirements.

Expanded access

Learn how to [request expanded access](#) of an investigational medical product outside of a clinical trial.

Reliance agreements

Learn how to [request reliance agreements for single IRB review](#) for human research studies.

Urgent Requests

Learn how to [submit an urgent request](#) for a one time, intentional action or process that will require an exception from the IRB approved protocol for one participant in the study, or how to work with the IRB to respond to sponsor Just-In-Time (JIT) requests.

Determination Form = Project Template

Section 1 & 2 include guidance material (instructions)

Section 3 is the actual project template

3.0 Description of Activity

If, after reviewing the information above, (1) you are unclear as to whether your activity is Human Research and would like for the IRB to make a determination for you or (2) you believe that your activity is not Human Research but would like for the IRB to provide documentation that it agrees with your assessment, then please complete the information below. **Delete the italicized instructions below when providing your information.**

3.1 Purpose

Briefly describe the purpose, specific aims, or objectives of the project.

3.2 Procedures

Describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any. For example, will the project include interviews, surveys, or other assessments? Will the interview questions focus on policies, practices, and/or procedures (e.g. the collected data does not focus on personal opinion or private information)?

3.3 Data and/or specimens

Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.

- **Data and/or Specimen Collection and Analysis**

Describe the data and/or specimens you will collect and how they will be analyzed.

- **Data and/or Specimen Collection Method**

Describe how you will obtain the data or specimens. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)

- **Identifiability of Data or Specimens**

Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the