TILBURG UNIVERSITY
School of Economics and Management

202401/V18

Submission Guide TISEM Institutional Review Board (IRB)

1. Which research needs to be reviewed by the TiSEM IRB?

All research with data relating to living humans or groups of living humans to be conducted by TiSEM faculty, PhD candidates, Research Master students, and Master students under supervision of a faculty member or a PhD candidate at TiSEM when the purpose is to publish the student's research (from now on called "researchers") needs IRB approval. Exemptions are granted for the following situations:

1. Research using existing anonymized data
2. Research using existing pseudonymized data for which the key to link the data to persons is **not** available in the research team
3. Research using existing data from a Tilburg University approved database, only **after** review by the Data Representative

For details on whether you need TiSEM IRB approval and what to submit see: Do I need TiSEM IRB approval and the website page for researchers.

Joint research

- When research is carried out in collaboration with researchers not from TiSEM and approval for (1) data collection, (2) data management and (3) GDPR for the proposed research is available from an IRB or Ethical Review Board (ERB) of another school within Tilburg University or an accredited university (AACSB or equivalent), one should submit the approval letter with the original research proposal to TiSEM IRB.
- If joint research does not have approval on the above points, the principal investigator (PI) needs to file an IRB approval within TiSEM.

2. Submitting applications for review

2.1 Types of application

Individual TiSEM researchers can submit the following types of application:

- An application for **full** or **expedited** review of a new individual research project.
- An application **exempt** from full review which includes research within a **Standard Research Protocol** (SRP) and research **approved by another accredited IRB** on data collection, data management, and the GDPR.
- An **amendment** to an approved application with no increased risk for participants.

2.2 Application procedure

2.2.1. Determine which type of application you need to submit to the IRB. When in doubt, contact the IRB manager for support.

2.2.2. Complete the submission form and add the appendices according to the type of application. The information required for each type of application is described here.

2.2.3. Submit your application by e-mail to the IRB (irb-tisem@tilburguniversity.edu).

2.2.4. Upon submission you will receive a confirmation of receipt of the application and an IRB submission number. Use the IRB number in further communications with the IRB.

2.3 Language

2.3.1. The submission form is completed in English.

2.3.2. The appendices (information letter, consent form, debriefing, surveys, etc.) are in the language in which the proposed research is executed. If the language is not Dutch or English than the researcher is responsible for a translation into English.

2.4 Review procedure

Full review

Applications are submitted by e-mail and reviewed independently by the data representative and two other IRB members using the review form. They have 10 working days to review the application. The chairperson makes the decision about the outcome of the reviews.

Expedited review

Applications are submitted by e-mail and reviewed independently by the data representative and the chairperson using the review form. They have 10 working days to review the application. The chairperson makes the ultimate decision about the outcome of the reviews.

Exempt from full review

Applications within an approved Standard Research Protocol (SRP) are submitted by e-mail and reviewed by the data representative and the chairperson. They have 5 working days to check the application's adherence to the SRP. The chairperson makes the ultimate decision about the outcome of the reviews.

Applications for research that received approval from an Ethical Review Board (ERB) of another school within Tilburg University or another accredited university (AACSB or equivalent) are submitted by e-mail for ratification. It is sufficient to submit the approval letter with the original research proposal. The IRB has 5 working days to ratify the application.

Amendment

Applications are submitted by e-mail and reviewed independently by the data representative and the chairperson, if the changes are minor (all questions in part 3.3 of the submission form are answered with "no"). They have 5 working days to review the application. The chairperson makes the decision about the outcome of the reviews.

Standard Research Protocols

Proposals for a new 'Standard Research Protocol' in addition to the existing SRPs are reviewed by the entire IRB committee. The IRB makes the decision about the outcome of the review by majority at a meeting at which at least half of the committee members are present.

- All researchers can propose a Standard Research Protocol with other researchers from the same or another Department at TiSEM.
- A SRP is a typical way of doing research in a specific Department, (sub)discipline, or across Departments. Individual studies conducted in the context of a Standard Research Protocol share methodological and data characteristics, and can — but need not — share substantive (content) characteristics. Thus, individual studies conducted as part of a Standard Research Protocol make use of similar data collection procedures, data management procedures, and have similar GDPR characteristics.
- A SRP description provides, in more detail than for a single study, the details of data collection, data management, and GDPR information of the typical studies conducted in its context. An extended TiSEM IRB form is used, and appendices for the relevant documents (consent form, debriefing, etc.) are added. Information about one or more typical, specific studies in the context of the protocol could be included.

- The extended TiSEM IRB form has the same questions/items as the regular form but allows more space for details.
- Each SRP has a coordinator who informs and supports researchers and the IRB when necessary.
- The application for a SRP should be submitted by e-mail to the IRB.
- Upon submission, you receive a confirmation of receipt of the application, and an IRB submission number. Use the IRB number in further communications with the IRB.

2.5 Review criteria

2.5.1. Status of reviewed applications is: approval, revision needed, or rejection.

2.5.2. IRB will advise the applicant(s) to submit the application to a Medical Research Ethics Committee (MREC) if applicable.

2.5.3. The IRB communicates about the proposal with the PI.

2.5.4. Research proposals are evaluated on:

a. Ethics of data collection
    - Fully inform participants about the data collection procedure and the intended use of their personal data.
    - Obtain informed consent from participants before starting data collection.
    - Prevent as much as possible any physical and/or psychological harm or strain to participants from the data collection.
    - Assess whether and to what extent you have achieved this goal.
    - Take immediate remedial action to solve any problems that have arisen due to or during data collection.

b. Data management and GDPR
    - Transparency in data management by documenting which data are stored where and how and who has access to this.
    - Privacy protection of the participants.
    - Accessibility of data and procedures to contribute to the replicability and reproducibility of research results.

3. Appeal and complaint procedure

Researchers can appeal and complain about the outcome of the review process or the review procedure. The IRB treats these appeals and complaints in an open and solution-focused atmosphere.

The appeal and complaint procedure of the IRB is as follows:

a. The researcher discusses their appeal and/or complaint with their immediate supervisor and with the IRB manager to provide clarification and/or find a satisfactory solution.
b. If (a) does not lead to a satisfactory solution, a written appeal and/or complaint is submitted to the IRB chairperson (irb-tisem@tilburguniversity.edu), who responds in writing within 5 working days.
c. If (b) does not lead to a satisfactory solution, a written appeal and/or complaint is submitted to the Vice-Dean for Research, who makes a final decision and communicates this, including the reasoning, to the researcher involved and the IRB chairperson.

4. Compliance with IRB principles

It is the responsibility of individual researchers:

a. To obtain IRB approval before conducting research that falls within the scope of the IRB.
b. To provide correct and complete information about the planned research to the IRB with the purpose of obtaining approval.
c. To start the research only after having obtained IRB approval.
d. To only deviate from an approved research proposal after having obtained permission of the IRB for this.
e. To discuss own or another researcher's noncompliance with these principles with the Tilburg University confidential advisor on academic integrity and/or to report the issue to the Tilburg University Committee for Scientific Integrity.

Investigating non-compliance with the IRB principles by researchers is not within the scope of the IRB.

For more information: Netherlands Code of Conduct for Research Integrity.

5. Contact and support

In case of questions related to the IRB, check the IRB website or contact the IRB manager (Juliana Thomazini, irb-tisem@tilburguniversity.edu).