

## TISEM IRB OPERATING PROCEDURE

### 1. TiSEM IRB

#### Article 1. Name

TiSEM IRB stands for Institutional Review Board (IRB) of the Tilburg School of Economics and Management (TiSEM) of Tilburg University.

#### Article 2. Composition

The composition of the IRB is specified in the IRB Regulations.

#### Article 3. Tasks of the chairperson

- 3.1. The chairperson opens, closes, and chairs the meetings of the IRB.
- 3.2. The chairperson draws up the agenda, prepares it, and follows it in collaboration with the IRB manager.
- 3.3. The chairperson signs the correspondence and other documents on behalf of the IRB.
- 3.4. The chairperson makes the final decision about the status of research applications.

#### Article 4. Vice chairperson

- 4.1. The chairperson chooses a vice chairperson from among the IRB members.
- 4.2. The vice chairperson replaces the chairperson in case the latter is temporarily unavailable and is accessible for consultation by the chairperson for example in case of complex situations.

## **2. Management**

### **Article 5. Tasks of the IRB manager**

- 5.1. The IRB manager carries out all activities in cooperation with the chairperson.
- 5.2. The IRB manager prepares meetings and ensures that all documentation during the meetings is available to the IRB members.
- 5.3. The IRB manager checks that the status of an application is correct and that the application is complete.
- 5.4. The IRB manager follows up on IRB decisions.
- 5.5. The IRB manager, in consultation with the chairperson, ensures that the review procedure, as described in article 11, is followed.
- 5.6. The IRB manager maintains communication with the applicants.
- 5.7. The IRB manager maintains communication with the IRB members.
- 5.8. The IRB manager maintains communication with the other Tilburg University E/IRB's.
- 5.9. The IRB manager maintains the database of all submitted research proposals.
- 5.10. The IRB manager prepares the annual report.

## **3. Autonomy and Confidentiality**

In addition to the Netherlands Code of Conduct for Research Integrity (specifically section 3.5), the IRB members adhere to the following:

### **Article 6. Autonomy**

- 6.1. An IRB member reviews applications and participates in the IRB autonomously, without conflicts of interest.
- 6.2. An IRB member does not review individual research applications in which they are involved as applicant, external expert, advisor, or in any other relevant capacity.
- 6.3. An IRB member does not review applications that involve other interests for them including financial, family or friendship relationships, intellectual property rights or involvement in one or more interest groups, or sectors that might benefit from the outcomes for the proposed research.
- 6.4. If an IRB member believes that they have a possible conflict of interest, they indicate this to the chairperson as soon as possible. If the chairperson decides that the stated interests do indeed lead to a conflict of interest, or that third parties may have reasonable doubt about the autonomy of the IRB member in the case, the member is not involved in the discussion and review of the application.

**Article 7. Confidentiality**

IRB members and the IRB manager observe strict confidentiality about all information concerning the content of the research applications and the review procedure of the IRB.

**Article 8. Declaration of Autonomy and Confidentiality**

IRB members sign a declaration of autonomy and confidentiality at the beginning of their term of office. Appendix 1 contains the declaration. In case an IRB member violates the content of the declaration of autonomy and confidentiality, the chairperson considers the arguments and decides on the measures to be taken. In case the chairperson is not able (being involved and/or not available) to act the vice chairperson takes this role. In case the vice chairperson is also not able to act the Vice Dean for Research takes this role.

**Article 9. Internal communication on proposals**

- 9.1. An overview of the submitted applications (title of research proposal, researchers involved, type of application, IRB numbers and status) is available information, to which IRB members have access upon request.
- 9.2. Submitted applications can be inspected by IRB members upon request, after the application in question has received a status code (accept, reject and revision). IRB members cannot share the information with other people, besides other IRB members. See *Declaration of autonomy and confidentiality signed by TiSEM IRB members*.

**4. Procedure for submitting applications**

**Article 10. Website IRB**

The website of the IRB includes information on the composition of the IRB, contact information, and procedural information.

**Article 11. Submitting applications**

- 11.1. The procedure to submit an application for review is described in the Submission Guide.
- 11.2. The IRB manager evaluates the completeness of the application for review.

## 5. Procedure for reviewing applications

### Article 12. Review of applications

- 12.1. Types of submission:
- a. Submissions for the development of 'Standard Research Protocols' are reviewed by the entire IRB committee and the data representative. The IRB makes the decision about the outcome of the review by a majority vote of the number of members in the IRB committee at a meeting at which at least the majority of the number of members in the IRB committee is present.
  - b. Submissions for status "full review" are reviewed independently by two members of the IRB and the data representative. The chairperson makes the decision about the outcome of the reviews.
  - c. Submissions for status "expedited" are reviewed by the data representative and the chairperson. The chairperson makes the ultimate decision about the outcome of the reviews.
  - d. Submissions for status "exempt from full review" are reviewed by the data representative and the chairperson. The chairperson makes the ultimate decision about the outcome of the reviews.
  - e. Amendments or renewals of approved applications are reviewed by the chairperson and data representative, if the changes are minor (all questions in part 3.3. of the submission form are answered with 'no'). Amendments or renewals of approved applications are reviewed by two members of the IRB committee and the data representative, if the changes are major (not all questions in part 3.3. of the submission form are answered with 'no').
- 12.2. IRB members use the review form to review each application.
- 12.3. All decisions of the IRB take into account the advice on GDPR and research data management.
- 12.4. Status of reviewed applications is: approval, revision needed, or rejection.
- 12.5. The IRB reviews 'Standard Research Protocols' within a maximum of 30 working days from the date of application, first submissions for "full review" in 10 working days, "expedited" in 10 working days, and "exempt from full review" proposals within 5 working days.
- 12.6. The IRB will advise the applicant(s) to submit the application to a Medical Research Ethics Committee (MREC) if applicable.
- 12.7. In principle, the IRB does not review proposals for which primary data has already been collected.

**Article 13. Accountability**

Members of the IRB cannot be held personally accountable for a decision of the IRB and potential outcomes of the decision.

**6. Meetings**

**Article 14. Location**

14.1. The chairperson determines the number of meetings.

14.2. The IRB manager determines the location of meetings of the IRB and communicates it to the members together with the agenda.

**Article 15. Agenda**

15.1. The agenda of each meeting shall be sent to the members by e-mail at the latest five working days before the meeting.

15.2. Each member may have an item placed on the agenda for discussion. The member sends the item, at the latest, one week before the scheduled meeting to the IRB manager. The IRB manager adds the item to the draft agenda which is sent for approval to the chairperson.

**Article 16. Minutes**

After each meeting, minutes shall be drawn up and shared with the members.

**7. Data management**

**Article 17. OneDrive**

All information of the research proposals is stored on OneDrive.

**8. Approval and Revision**

**Article 18. Approval Operating procedure**

18.1. The Operating procedure of the IRB was approved by consensus by the IRB on November 5, 2019 and entered into effect January 1, 2020.

18.2. The Operating procedure may be amended by a majority vote of the IRB committee.

18.3. In cases not provided for in the IRB Operating procedure, the chairperson shall decide.

**Article 19.      Revision clause**


- 19.1.      Every year, the IRB evaluates the present internal regulations and reports on them in writing in the annual report in accordance with Article 5.
- 19.2.      The Operating procedure may be amended ad hoc by mutual agreement or as a matter of urgency at the proposal of the chairperson. They shall also be reported on subsequently in the annual report.

**9. Compliance with IRB principles**

**Article 20.      Compliance**

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

## Appendix 1 – Declaration of autonomy and confidentiality of TiSEM IRB members

	
<b>Declaration of autonomy and confidentiality of TiSEM IRB members</b>	
<p>I hereby declare and confirm with my signature that, as a TiSEM Institutional Review Board (IRB) member &lt;start and end date of term&gt;:</p> <ol style="list-style-type: none"><li>1. I will act independently of any external influence, when reviewing applications and recording general and organizational matters.</li><li>2. I will only review individual research applications:<ol style="list-style-type: none"><li>a. in which I am not involved as applicant, external expert, advisor, or in another relevant capacity.</li><li>b. that do not involve other interests for me including financial, family or friendship relationships, intellectual property rights or involvement in one or more interest groups, or sectors that might benefit from the outcomes for the proposed research.</li><li>c. in which I do not have a personal or professional conflict with the applicant(s).</li></ol></li><li>3. In case of a possible conflict of interest, I will indicate this to the chairperson of the IRB as soon as possible. In case this conflict holds to the chairperson I will indicate this to the vice chairperson of the IRB as soon as possible.</li><li>4. I will observe strict confidentiality about all information concerning the content of the research applications and the review procedure of the IRB both during my membership and afterwards.</li><li>5. I will comply to the internal regulations of the IRB, which are available on the IRB website.</li></ol>	
Name	
Place	
Date	
Signature	