



TiSEM IRB (Institutional Review Board)

Rik Pieters (August 25, 2020)

Program

- Opening
- TiSEM Institution Review Board (IRB)
Rik Pieters, chairperson TiSEM IRB)
- Research data management and privacy regulations
Pam Dupont, TiSEM Data Representative
- Closing

Questions are gifts – Ask questions



TiSEM Institution Review Board (IRB)

The Spanish Inquisition – Squared?



- No-no-no-no.

IRB mission and guiding principles (1)

To evaluate research proposals on:

- Ethics of data collection
 - **Fully inform** participants about data collection procedures and 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 data collection
 - **Assess** to what extent **this goal** has been achieved
 - Take immediate **remedial action** to solve any problems due to or during data collection
- 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

IRB mission and guiding principles (2)

To sustain and improve the quality of research at TiSEM for:

- a. Participants: Protect the privacy of participants and prevent physical, psychological or other harm to participants in research.
- b. Institution and Society: Support and facilitate integrity and transparency of data collection and management, and accessibility of research data and results to the extent that this does not conflict with a.
- c. Researchers: Support, educate, and aide researchers to conform to the IRB aims and procedures at the minimum possible workload for researchers, to the extent that this does not conflict with a. and/or b.



TiSEM Institutional Review Board

The TiSEM IRB is a permanent and independent committee established by TiSEM's management team.

- All US medical and social science schools (since the 1974 National Research Act), and increasing numbers of schools of economics and business in the US and elsewhere have an IRB.
- Top journals increasingly ask for IRB approval during article submission.
- National and International granting institutions (NWO, NSF) increasingly require IRB approval
- The VSNU (Netherlands Code of Conduct for Research Integrity October 2018) calls Dutch universities to have ethical review of research conducted at their institutions.
- Tilburg University (Scientific Integrity Plan, June 8, 2018) calls all its schools to have an “Ethics/data management committee/review board.”
- All schools at Tilburg University (TLS, TSB, TSHD, TST, TiSEM) have an IRB.
- Researchers want to treat their participants and society as they would want to be treated themselves.
- It helps researchers to plan their research



Scope

All research with data relating to living human subjects or groups of human living subjects conducted by TiSEM faculty, TiSEM PhD candidates, and TiSEM Research Master students (from now on called: researchers) needs IRB approval, **except**: ...



- a. research using anonymized existing data and
- b. research using pseudonymized, existing data for which the key to link the data to living human subjects or groups is not available in the research team.



- The IRB does **not** review the scientific contribution and/or societal relevance of the proposed research.
- Proposed research can be conducted after having received IRB approval.
- The IRB cannot provide post-hoc approval after research has started or has been completed.

Phasing

- 2019: on a voluntary basis
- January 2020
 - Research Master students at TiSEM under the supervision of a faculty member or a PhD candidate at TiSEM
 - TiSEM PhD candidates
- September 2020
 - Faculty working at TiSEM
 - Master's students at TiSEM : research by Master's students that *may be used* by faculty or PhD candidates for future publication.
 - Application for IRB approval is done by the faculty member or PhD candidate in question.

Do I Need IRB approval? (1)

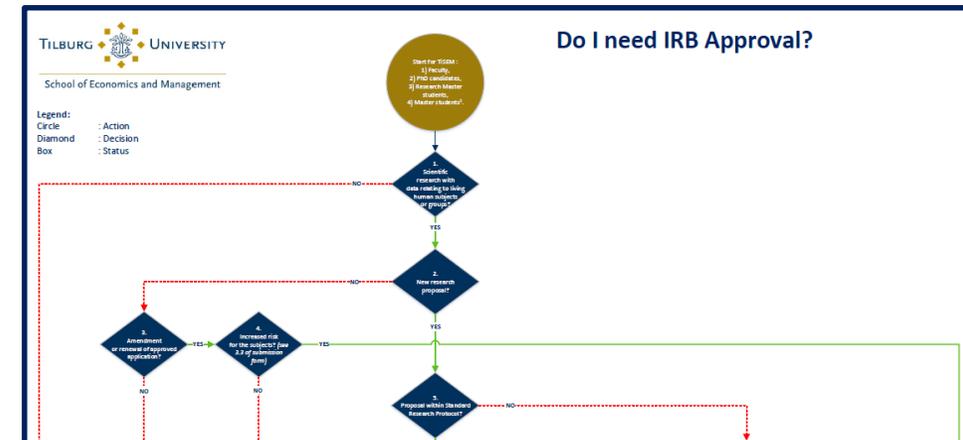
Do:

1. Go to TiSEM IRB website : <https://www.tilburguniversity.edu/research/economics-and-management/institutional-review-board>

2. Click on : **Information for Researchers** →

3. Check the flowchart : **Flowchart 'Do I need IRB approval'** →

4. For any questions : **Contact us** ^



Do I Need IRB approval? (2)

Seven outcome categories: **Green** boxes at the bottom

A. No IRB review required

- Complete submission form part 2B and keep in your personal files

B. Exempt I (*Amendment/renewal with no increased risk for subjects*)

- Provide approved application with 'track changes' and sign parts 3.2 and 3.3 of submission form

C. Exempt II (*Proposal within Standard Research Protocol*)

- Complete submission forms parts 1 and 3

D. Expedited

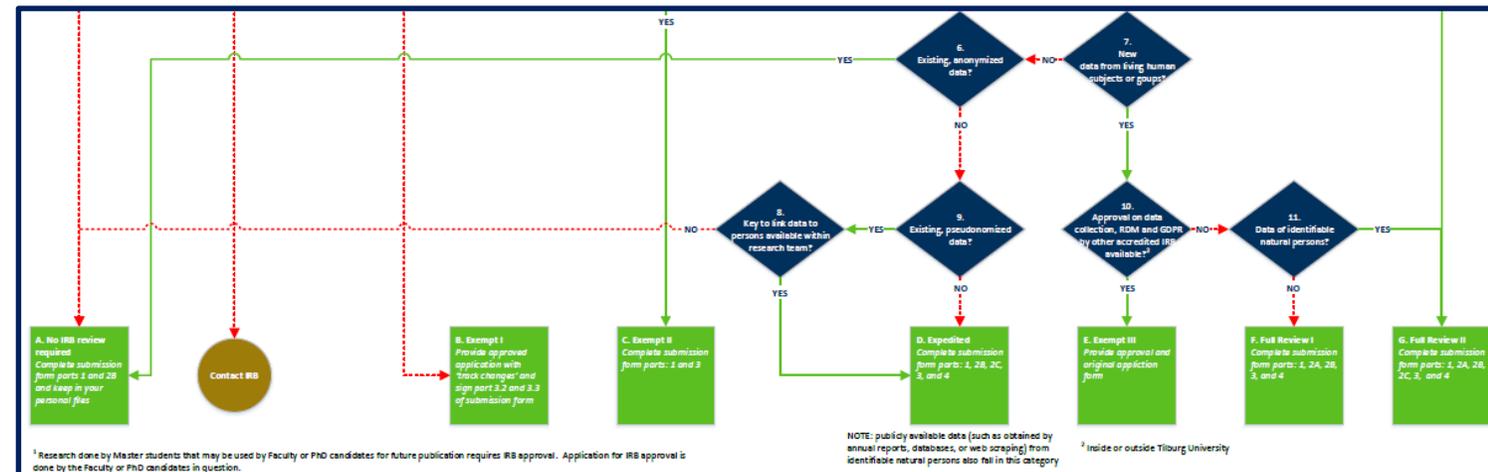
- Complete submission forms parts 1 and 3

E. Exempt III (*Approval on data collection, RDM and GDPR by other accredited IRB available*)

- Provide approval and original application form

F. Full Review I

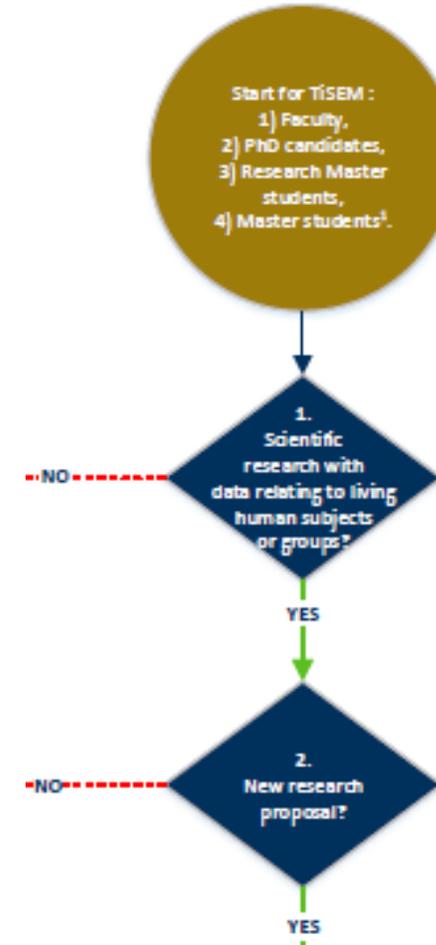
G. Full Review II



Do I Need IRB approval? (3)

To get to an outcome category:

1. Start at the top (circle)
2. Answer a minimum of 1 and a maximum of 11 questions (blue diamonds)

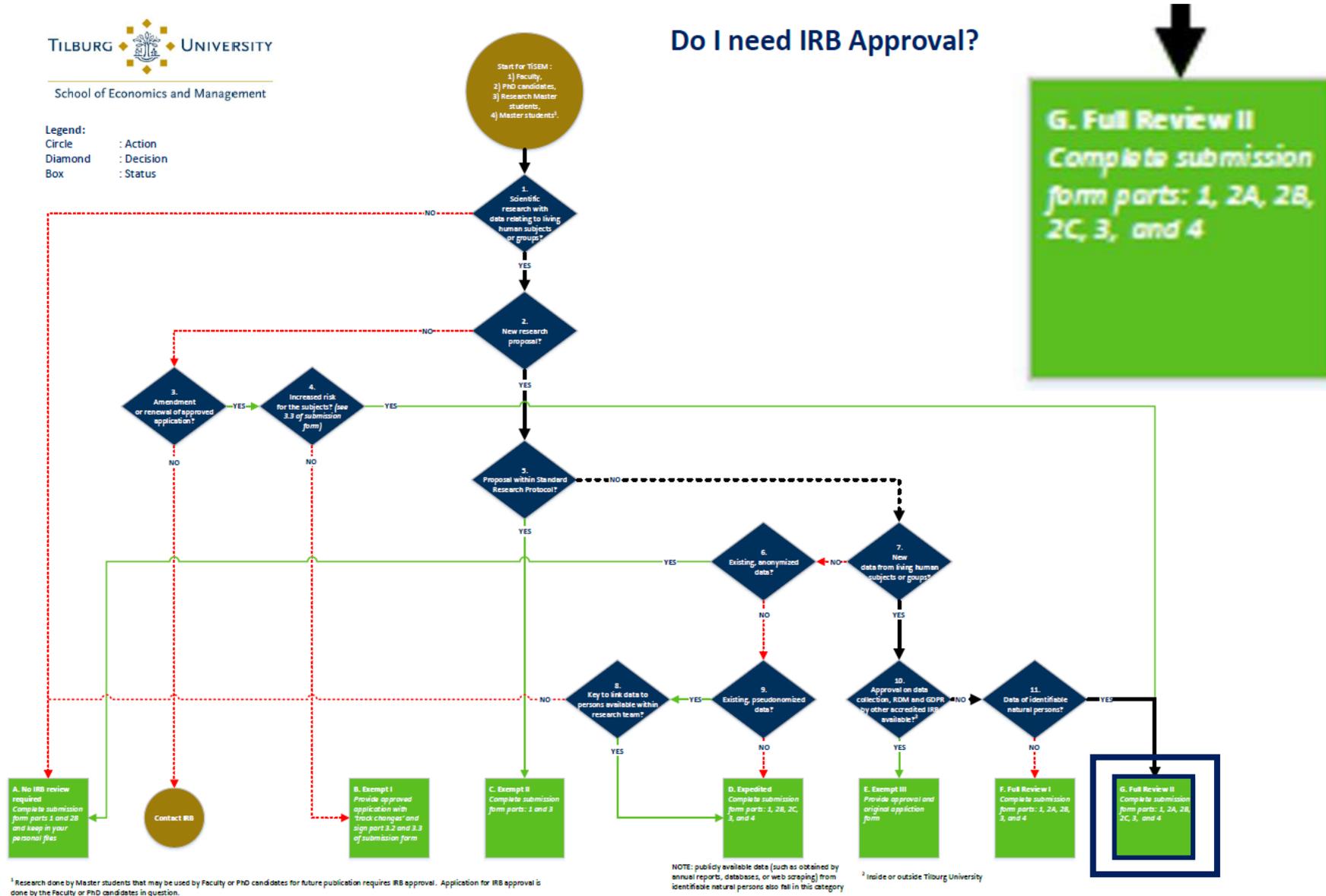


1. Research done by Master students that *may be used* by Faculty or PhD candidates for future publication requires IRB approval.

Example project 1

Natural field experiment:
An experiment conducted in a real-life setting in which participants are unaware that they are part of an experiment.

Legend:
Circle : Action
Diamond : Decision
Box : Status

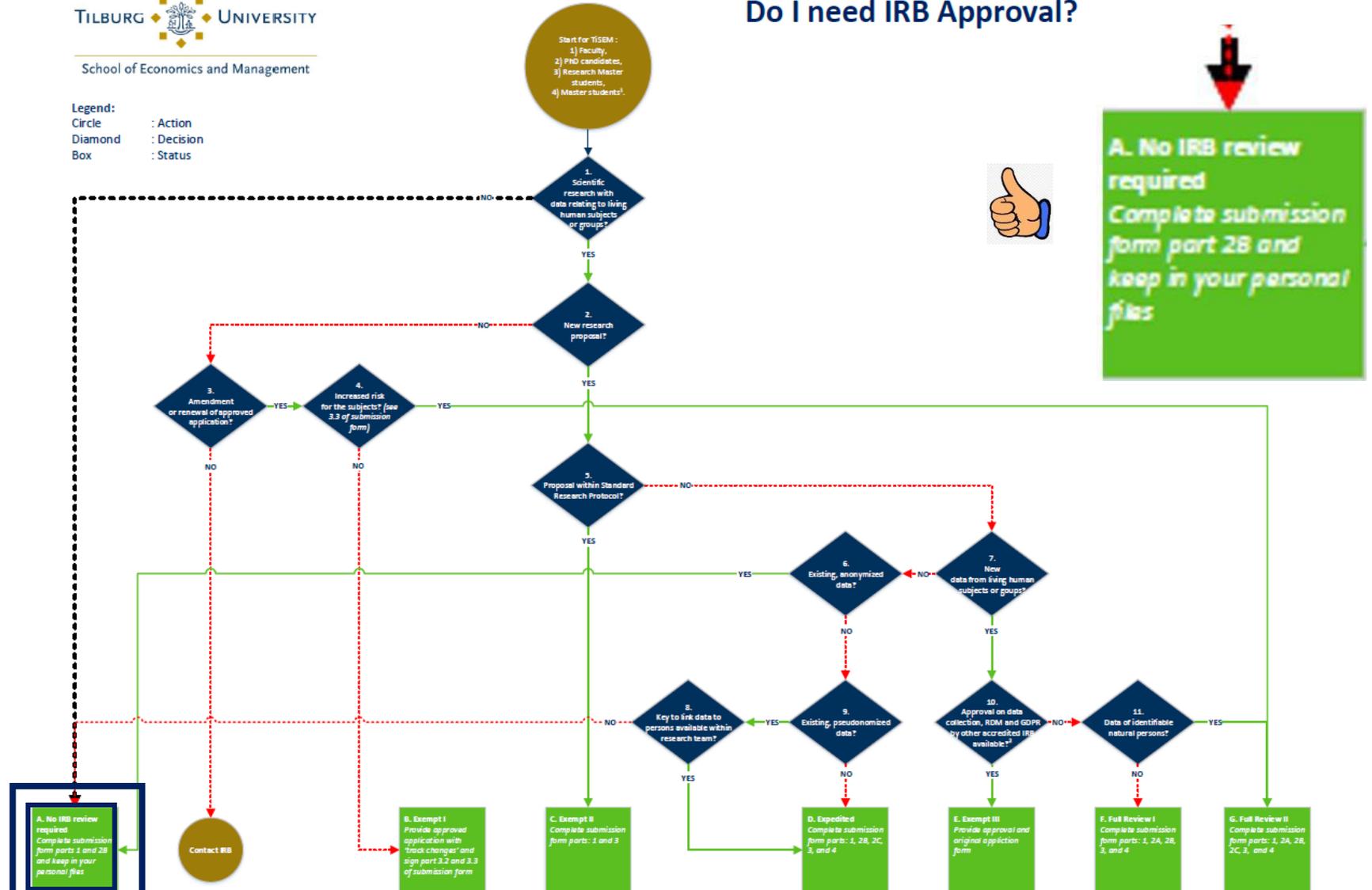


Example project 2

Research using existing data about human subjects from historical sources usually stored in archives or libraries.

The information is about individuals who are already deceased.

Legend:
Circle : Action
Diamond : Decision
Box : Status



Do I need IRB Approval?



A. No IRB review required
Complete submission form part 2B and keep in your personal files

¹ Research done by Master students that may be used by Faculty or PhD candidates for future publication requires IRB approval. Application for IRB approval is done by the Faculty or PhD candidates in question.

NOTE: publicly available data (such as obtained by annual reports, databases, or web scraping) from identifiable natural persons also fall in this category

² Inside or outside Tilburg University

Example project 3

Experiments in the CentER lab or on a crowdsourcing platform (e.g., Mturk).

Participants make choices that have an influence on the amount of money that they (and possibly other participants) earn.

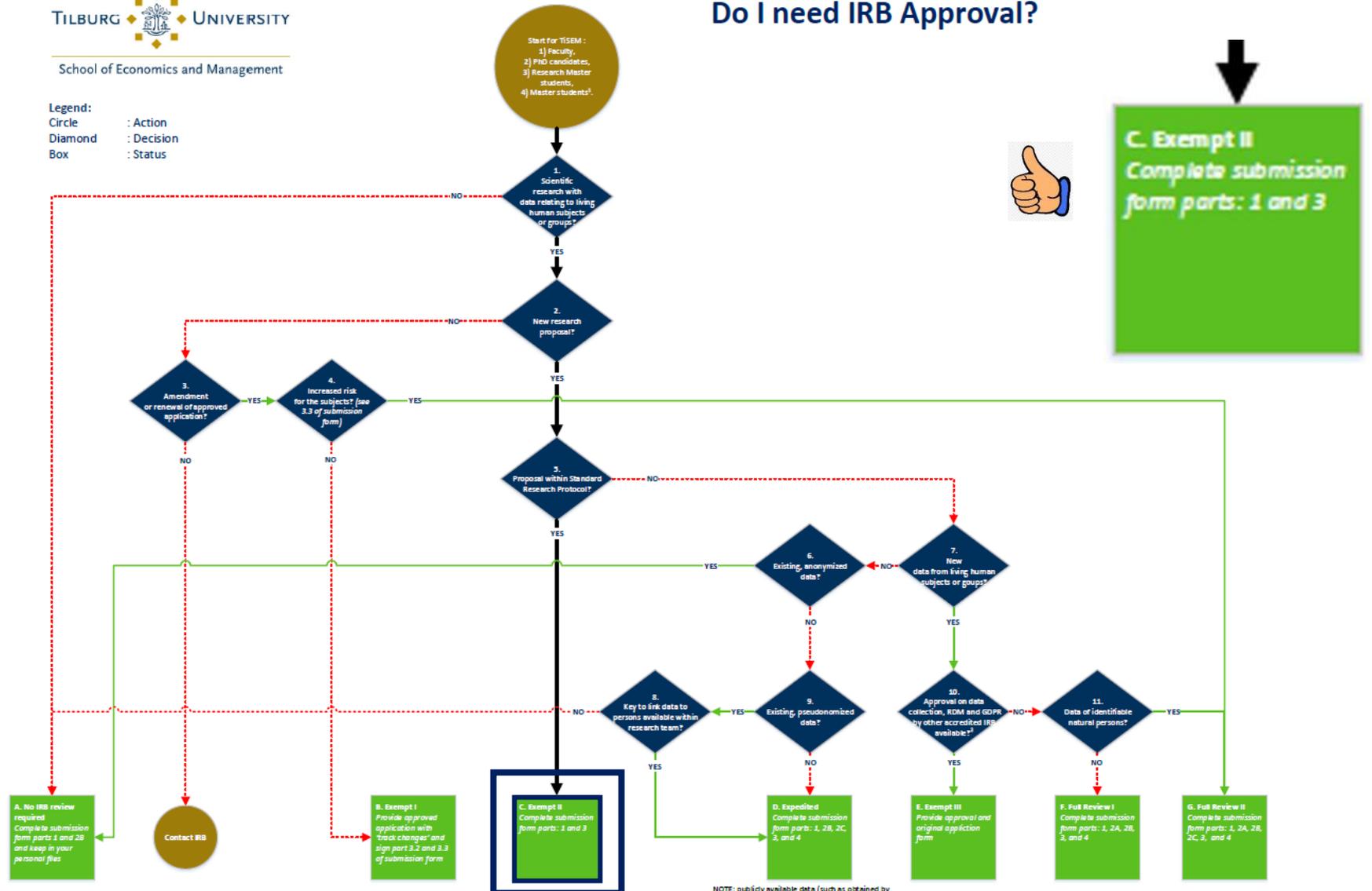
The choices are fully anonymous and are not linked to personal data.

There is no deception, little risk and everything included in the instructions is real.

Falls under SRP.



Legend:
 Circle : Action
 Diamond : Decision
 Box : Status



Do I need IRB Approval?



C. Exempt II
 Complete submission form parts: 1 and 3

¹ Research done by Master students that may be used by Faculty or PhD candidates for future publication requires IRB approval. Application for IRB approval is done by the Faculty or PhD candidates in question.

NOTE: publicly available data (such as obtained by annual reports, databases, or web scraping) from identifiable natural persons also fall in this category

² Inside or outside Tilburg University

Collaborative research

- Research carried out in collaboration with organizations other than Tilburg University
 - The research proposal describes the role of each organization in the research.
 - TiSEM IRB approval is required when the research falls within the scope of TiSEM IRB.
 - No TiSEM IRB review is required when approval for data collection, data management and GDPR for the proposed research is granted by another accredited IRB: submit the approval letter with the original research proposal to TiSEM IRB.
 - The informed consent form and the information letter must be part of the research proposal, when the content of the data collection (such as sample composition, sampling, measurement instrument) is at least partly determined by Tilburg University.

In case of questions: irb-tisem@tilburguniversity.edu



Standard Research Protocol (SRP) – Streamlining IRB approval

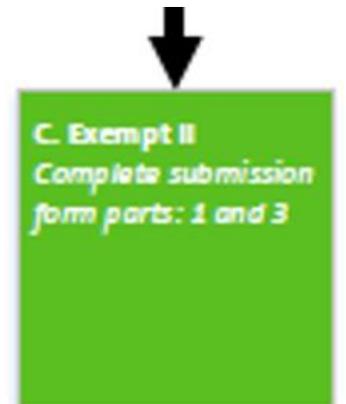
Research that falls under a SRP is **exempt** from IRB review.

It only requires minimal information from the researcher.

Research within an SRP shares the same research procedures.

SRP-1: “Incentivized Experiments in Economics and Business”

SRP-2: “Studies on Judgement and Decision Making”



Characteristics SRP-1

Experiments in this SRP have the following characteristics:

- Participants make **choices** between options.
- Participants receive a **financial remuneration** based on their choices (incentive compatible). Minimum earnings are typically not lower than 5 Euros per hour and the maximum per hour is typically not higher than 5 times the average payment.
- The experimental procedures involve **minimal risk** to the participants.
- The topics of the experiment are **not sensitive**.
- The experiment does **not** involve **deception**.
- Responses of participants are recorded and stored **anonymously**.
- Participation is on **a voluntary** basis and only after obtained informed consent from the participants.
- Participants are **predominantly Tilburg University students**.
- Data collection predominantly takes place in the **CentERLab of TiSEM**, or via the CentERLab registration, or via one or more of the following **external online data collection platforms** (Amazon M-Turk, Prolific), or via a market, opinion, or social research organization that is member of ESOMAR (www.esomar.org) (e.g., Kantar Group, a panel of CentERdata of Tilburg University, Survey Sampling Internal (SSI)).

Submission form

The principal investigator completes all required parts of the submission form:

- Part 1. General information
- Part 2. Research Proposal
 - Part 2A. Data collection
 - Part 2B. Data management
 - Part 2C. Compliance
- Part 3. Signatures and declarations
- Part 4. Supporting documents

... completely and in English.

Submission guide is available at the website:

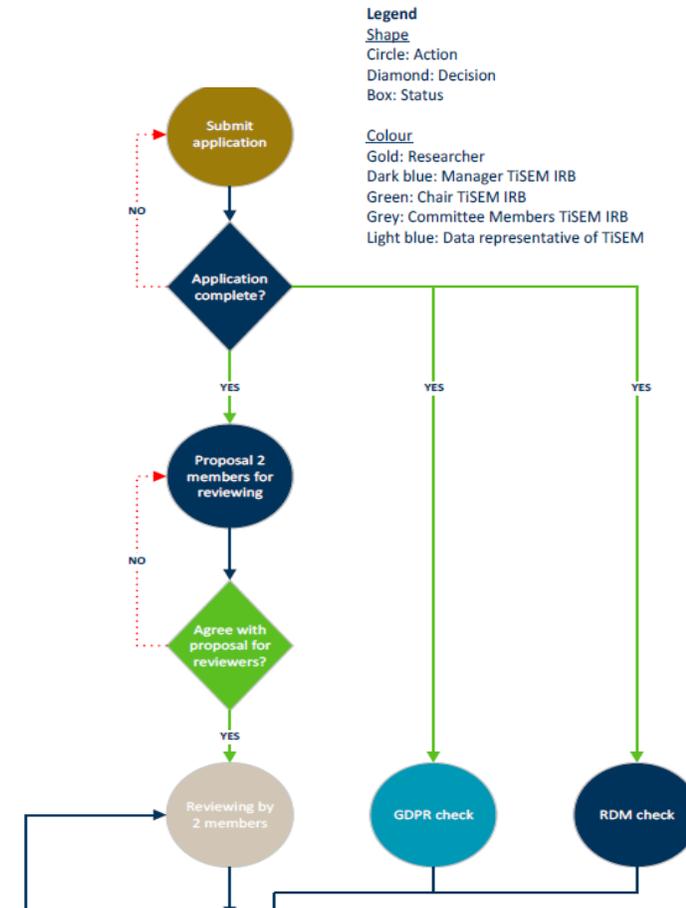
TiSEM IRB -> Information for Researchers -> Submission Guide



Review procedure full review (1)

As for a journal article but fast and constructive:

- Maximum 15 working days (for Full Review)
- With suggestions for improvement
- With help from IRB-manager if needed
- Maximum two rounds
- **Basic Process:**
 - Check if application is complete (IRB manager)
 - Assign two reviewers (IRB members or external experts)
 - GDPR check (data representative)
 - Remind reviewers after two weeks (IRB manager)
 - Combine reviews (IRB manager) and add recommendation (Chair)



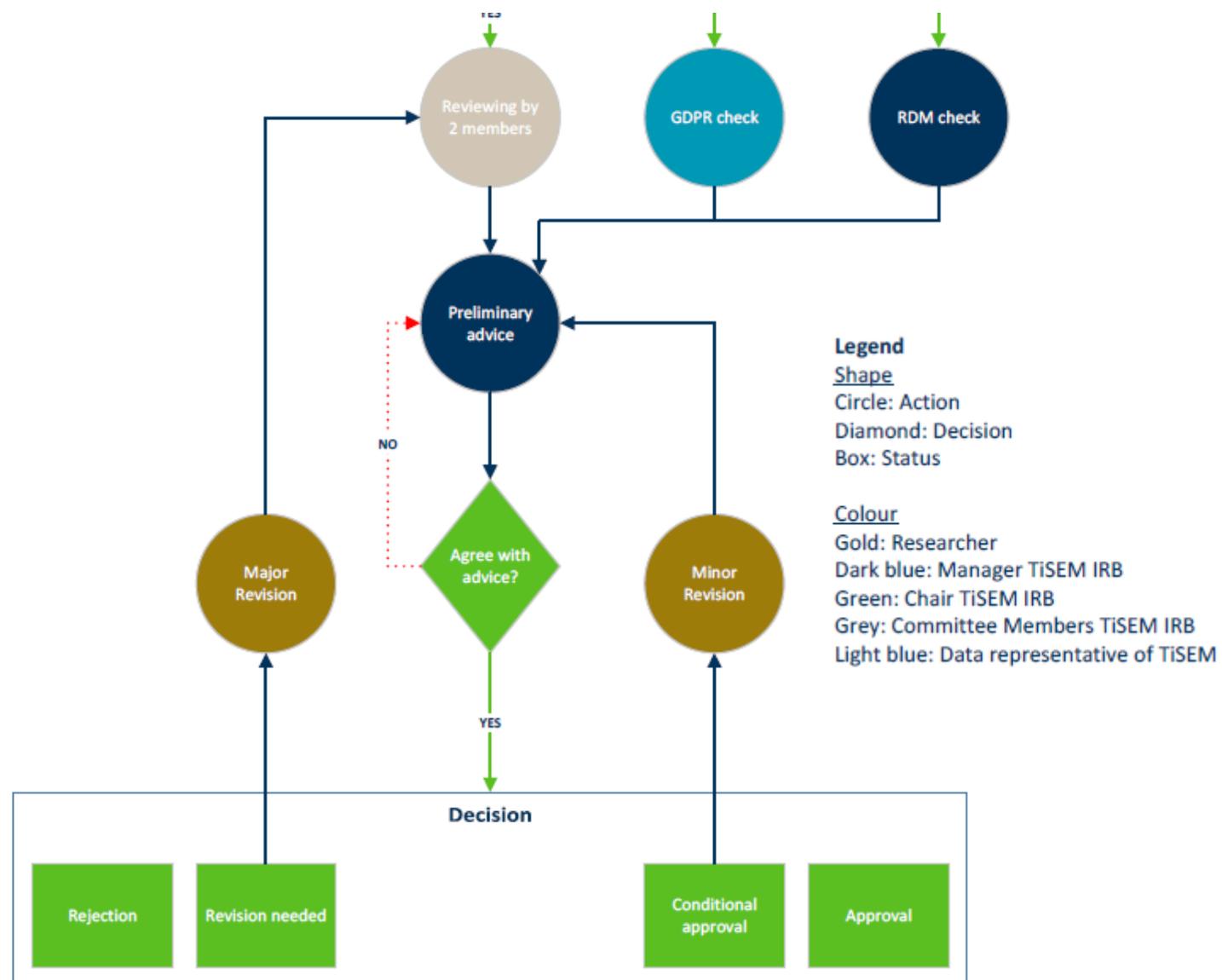
Review procedure full review (2)

Four Outcome Categories:

- Approval
- Conditional approval
- Revision needed
- Rejection

Review procedure:

<https://www.tilburguniversity.edu/research/economics-and-management/institutional-review-board/researchers>



Review procedure expedited (1)

Legend

Shape

Circle: Action

Diamond: Decision

Box: Status

Colour

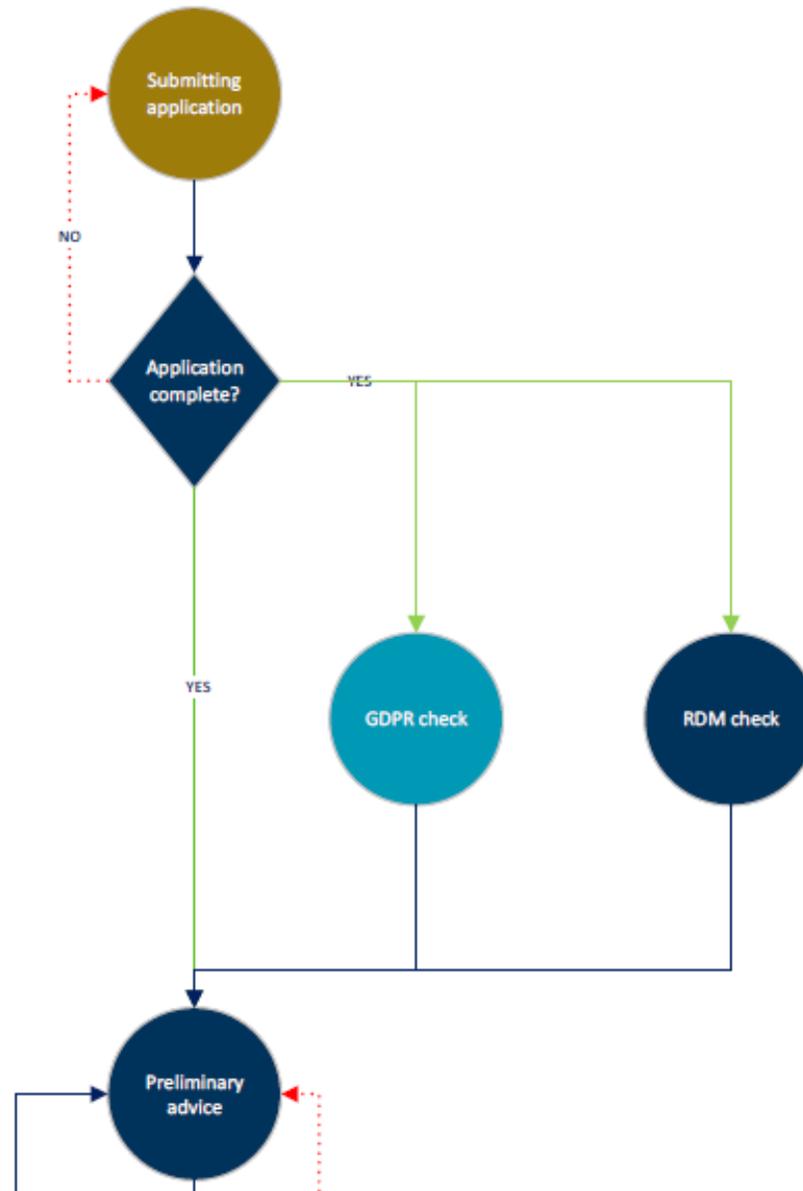
Gold: Researcher

Dark blue: Manager TISEM IRB

Green: Chair TISEM IRB

Grey: Committee Members TISEM IRB

Light blue: Data representative of TISEM



Review procedure expedited (2)

Legend

Shape

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Colour

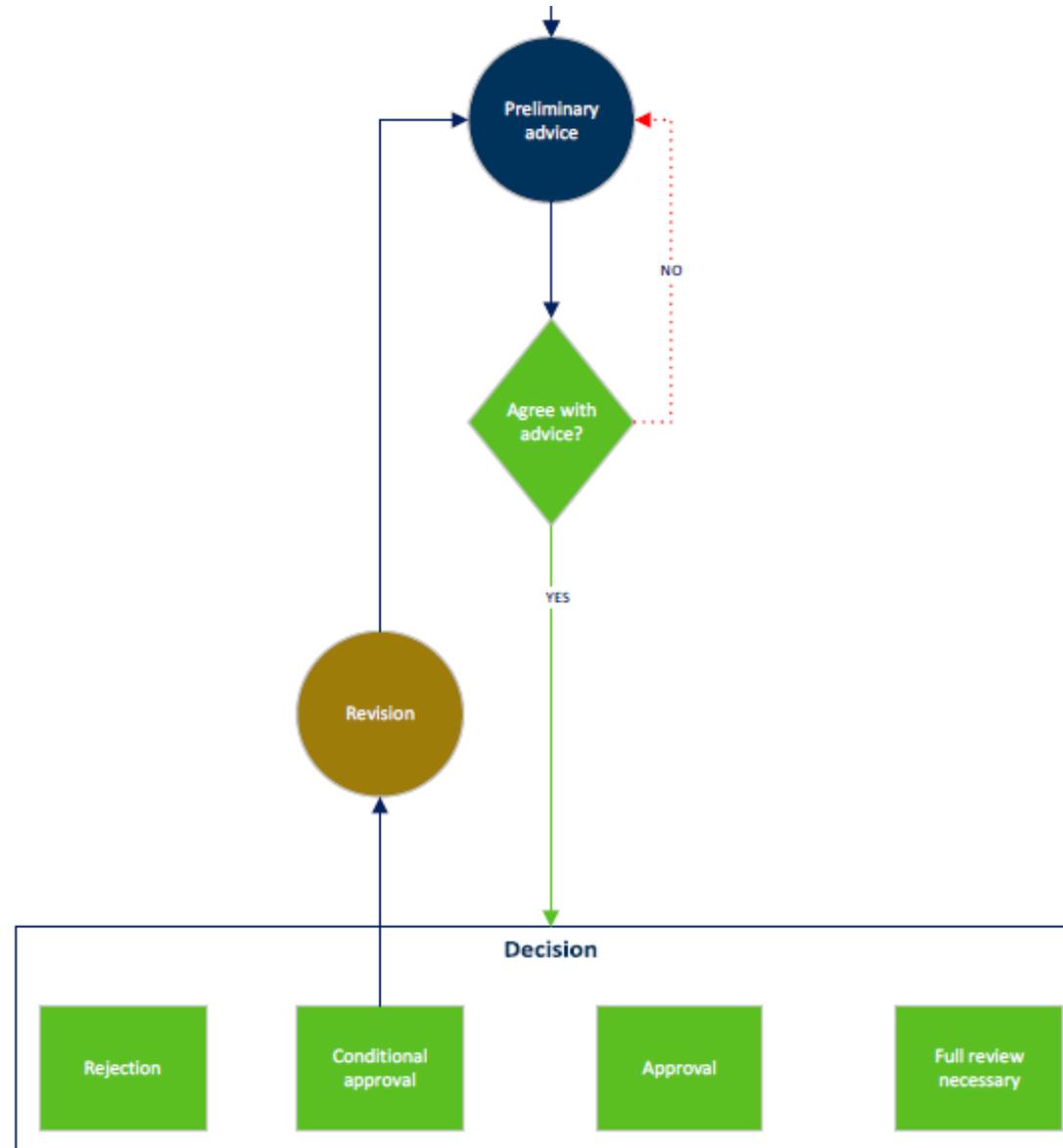
Gold: Researcher

Dark blue: Manager TISEM IRB

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Submitted proposals 2020 until now

| Proposals | Number | Department | Status |
|-------------|--|---|---|
| Full review | 7 | 1 Marketing 3 Economics 3 Management | 6 approval 1 at IRB members |
| Expedited | 2 | 2 Economics | 2 approval |
| Exempt | 16 • 12 within SRP-1 • 3 within SRP-2 • 1 exempt III (external IRB) | 10 Economics 4 Accountancy 1 Management 1 Econometrics | 15 completed 1 at other (external) IRB |

| Proposals | Range processing time (working days) | Average processing time (working days) |
|---------------------------------------|--------------------------------------|--|
| Full review (6) | | |
| First submission (6) | 7-11 | 9.33 |
| Resubmission revision needed (1) | 8 | 8 |
| Resubmission conditional approval (5) | 1-2 | 1.4 |
| Expedited (2) | | |
| First submission (2) | 2-7 | 4.5 |
| Resubmission (1) | 1 | 1 |
| Exempt (16) | 1-4 | 1.66 |

Compliance with IRB principles

It is the responsibility of individual researchers:

- To obtain IRB approval before conducting research that falls within the scope of the IRB.
- To provide correct and complete information about the planned research to the IRB with the purpose of obtaining approval.
- To start the research only after having obtained IRB approval.
- To only deviate from an approved research proposal after having obtained permission of the IRB for this.
- To communicate one's 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.

The TiSEM IRB does not investigate non-compliance with the IRB principles by researchers

Composition of the IRB from January 1, 2020

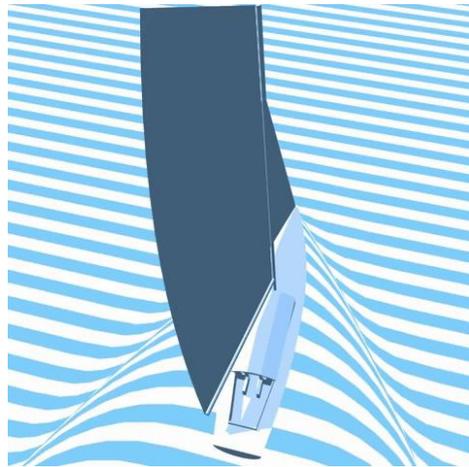
- Dr. Rik Pieters (Chair, Department of Marketing)
- Dr. Eddy Cardinaels (Vice Chair, Department of Accountancy)
- Dr. Tobias Klein (Department of Econometrics and Operations Research)
- Dr. Sigrid Suetens (Department of Economics)
- Dr. Ben Vollaard (Department of Economics)
- Dr. Carol Ou (Department of Management)
- Dr. Fabio Braggion (Department of Finance)

- Jantine Spithoven (IRB Manager, irb-tisem@tilburguniversity.edu)

More information: <https://www.tilburguniversity.edu/research/economics-and-management/institutional-review-board>

The Light House

- Yes, the IRB helps to ensure a safe and smooth, reproducible journey for research participants, researchers, the institution and society.



Research data management and privacy regulations