

DTU Compute's Institutional Review Board

December 9, 2019

1 Why do we need an IRB?

Experimental and computational research that employs human data has been expanding at DTU Compute. Something we need to carefully consider when working with human participants and human data is ethics and privacy. However, the research techniques we employ and the data we collect are mostly “safe”, as we do not collect data ourselves from any patient groups or use methods that carry risks or can cause harm to participants – and hence, much of this work does not require ethical approval at the national level. We strive to publish our work in top scientific journals (e.g. Neuroimage, Journal of Neuroscience, Nature, Science), but those journals require that the experimental proposals and ethical concerns have been approved by an ethical review board, and will otherwise not consider our papers. Since we are unable to obtain this from the national committee, we have a strong need for a more local, Institutional Review Board (IRB). In addition, the IRB would enable us to more carefully strive toward Safe AI.

2 What is the IRB responsible for?

This IRB is responsible for evaluation of ethical considerations for projects involving collection of any human data (i.e. through experiments), which do not fall within the area of competence and responsibility of the regional health sciences ethics committees. It is responsible for ensuring rights and well-being of participants, as well as good practice in data management and transparency of data, following guidelines in line with the Declaration of Helsinki. This will be ensured through evaluation of project proposals sent to the IRB; however, once approved, the responsibility lies with the applicants, as the IRB will not be responsible for guaranteeing that the applicants follow up on the regulations proposed in the report.

IRB approval should ideally be applied for prior to data collection. The committee will also grant approval for special cases where data collection has commenced or finished, if there are only minor ethical concerns, or where significant changes to the proposal are not required. (If data collection has commenced, this must be stated in the application).

The IRB will not review the scientific quality of the proposals. Also, it will not provide GDPR approval. It will, however, evaluate whether additional data protection approval is needed (in cases of partially anonymized or non-anonymized data) or not.

The IRB will primarily deal with projects of an experimental nature, with the goal of being published. It can also review student projects that require collection of data from human participants.

3 Committee members

The committee consists of VIP members across 5 different sections at DTU Compute, and two members from Administration/ITS:

Section for Cognitive Systems

- Ivana Konvalinka (chair of the IRB)
- Lars Kai Hansen
- Per Bækgaard
- Tobias Andersen

Algorithms, Logic and Graphs

- Paul Fischer

Image Analysis and Computer Graphics

- Tim B. Dyrby

Software and Process Engineering

- Andrea Burattin
- Ekkart Kindler

Statistics and Data Analysis

- Sofie Pødenphant Jensen

Administration/ITS

- Lene Hogg
- Henning Christiansen

The IRB will run as a pilot in the first year, after which we will evaluate any changes that need to be made in the protocol or committee.

4 Meetings and Evaluation Protocol

The IRB members will meet approximately once a month to review all the submitted applications. The applications should be emailed to irbboard@compute.dtu.dk, at the very latest 1-week prior to the meeting. All committee members present at the meeting should have read the applications. If an IRB member is involved in a submitted project proposal, they must step out of the discussion and not be involved in the project's evaluation. There must be a minimum of 3 sections represented at the meeting.

If there are any issues with the proposal, they will be addressed directly to the main applicant. Approval of the project is decided by a majority vote of the committee members that are present at

the meeting, excluding those who are involved in the project proposal. If the majority votes against approval, the proposal will be sent back to the investigator(s) with feedback notes. The applicant can then resubmit the proposal again.

The decision should be reached within 6 weeks of the submission. Approval will be sent in writing to the applicant(s), and a project number assigned to the application. All the applications and approvals will be stored in a common folder, shared by the committee members.

If any significant changes are made to the project proposals after acceptance, the changes will require further approval from the IRB.

5 Decision criteria

The basis for the committee's decisions is i) Act No. 593 of 14.06.2011 on science ethical treatment of health science research projects (as relevant to the projects); ii) Danish Code of Conduct for Research Integrity, Uddannelses- og Forskningsministeriet, Nov. 2014; iii) the 1975 Declaration of Helsinki as revised in 2008 (including §24 on informed consent); and iv) APA Ethical Standards in Publishing (APA Ethical Principles, 2010, section 8: Research and publication, including 8.14 on data retention and sharing).

The IRB will thus base their decision on the following criteria, ensuring that:

- there are no safety concerns for the participants in the proposed study, and if there are any, they are minor, and strongly motivated by the purpose of the study
- the participants will be informed in layman language of:
 - the purpose of the study
 - experimental procedures and duration of the study/experiment
 - confidentiality procedures
 - compensation (if any)
 - voluntary aspect
 - experimenters' contact info
- the participants will give consent via an informed consent form in which they will be made fully aware that their participation is voluntary and that they can withdraw at any time without explanation; the consent form will be signed and dated
- no deception will be used – if deception is used, there are strong reasons for it (i.e. concealing the purpose of the experiment)
- the participants will be treated with respect
- the participants will be debriefed at the end of the study, at which point all the information about the purpose has been given to them, if not before
- any unpleasant stimuli or situations are minor, discussed, and strongly motivated by the purpose of the study
- there are no invasive procedures (i.e. blood samples)

- the participants will not undergo any deprivation of water, food, sleep, etc.
- there is no drug administration
- mental patients or at-risk individuals will not be used
- data will be handled in a transparent manner
- the data are fully anonymized or pseudo-anonymized (the IRB will evaluate the method used)
- pseudo-anonymized and non-anonymized data are personal data and must be registered and treated according to DTU and department guidelines
- the results will be disseminated
- if data collection has already commenced or finished prior to approval, there are no major changes required for approval to the application, i.e. no major ethical concerns

6 IRB application format and documents

The ethics application should include the following information and documents:

- Project protocol (2-4 pages)
 - Title of project, names/affiliations of all the investigators involved
 - Motivation and background (including relevant references)
 - Study methods: design, measurements, protocols
 - Participant info: number of participants, recruitment procedures, inclusion/exclusion criteria, any reimbursement/compensation, debriefing
 - Data protection (is it fully anonymized, pseudo-anonymized, or non-anonymized – and how is this achieved?), handling, and dissemination of results
 - Ethical issues and considerations including informed consent (how it will be obtained), any deception used, risks and safety concerns, etc.
- Appendices
 - Informed consent forms (in English and Danish, if Danish participants are being used)
 - Information about the experimental purpose and protocols that will be provided to the participants, in layman language (in English and Danish)
 - Any questionnaires or material that will be given to the participants

7 Use of the ethics application approval from the IRB

Once the ethics application has been approved by the IRB, the applicants may use the following sentence (or similar) when writing up the study: “The study was approved by the Institutional Review Board at DTU Compute, Technical University of Denmark, *application number and date*”.