Research Ethics Committee

REC application questionnaire: List of questions

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About this list

- This list of questions is for reference only. To fill out an actual application applicants must use the webbased formular, not this list.
- This list of questions contains all questions in the questionnaire. When filling out an actual application via the webbased formular, the questionnaire will be adaptive. For instance, applicants will not be asked for PhD student and main PhD supervisor information, if the project is not a PhD project. Applicants will not be asked for information about informed consent procedures, if the project does not include human research participants, etc

Overview/table of questionnaire items

University of Southern Denmark
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Review eligibility

Please note:

- SDU's Research Ethics Committee reviews projects led by SDU faculty (post.doc, ass. professor, or professor) and PhD projects. Bachelor and master projects are not eligible for review.
- SDU's Research Ethics Committee reviews projects that are not eligible for review by the National/Regional Committees for Health Research or by the Animal Experiments Expectorate
- SDU's Research Ethics Committee reviews projects only before data collection has been initiated

Please choose the answer below that best describes your research project.

(1) ❑ Research project led by SDU faculty (post.doc., ass. professor, or professor)
(2) ❑ PhD project
(3) ❑ Bachelor or master project

Does the research project involve experiments on liveborn human individuals, human gametes intended for fertilization, fertilized human eggs, embryonic cells and embryos, tissue, cells and genetic material from humans, embryos etc. or deceased persons? This includes clinical trials of medicinal products in humans and clinical trials of medical devices.

(1) ❑ Yes
(2) ❑ No

Does the research project involve experiments with laboratory animals?

(1) ❑ Yes
(2) ❑ No

Has data collection and/or enrolment of research participants been started?

(1) ❑ Yes
(2) ❑ No

Project information

The research project's working title

_____

The research project's acronym, if available

_____

PhD student

Full name _____

Email _____

Department _____

Research unit/group _____

Main PhD supervisor

Full name _____

Email _____

Department _____

Research unit/group _____

Primary investigator

Full name _____

Email _____

Department _____

Research unit/group _____

Collaborating investigators (if any)

Please add contact information, including institution affiliation, for up to five collaborating researchers

Name and institution affiliation _____

Planned start of participant enrolment and/or data collection

Planned start date (yyyy-MM-dd) _____

Planned end date (yyyy-MM-dd) _____

Please state the project's source(s) of funding

_____

If you have, will or plan to receive funding, please discuss possible conflicts of interest and impact on the independence of your research arising from this source of funding.

_____

What are your reason(s) to apply for research ethics approval for this project?

(1) ❑ It is required or expected to be required for publication
(2) ❑ It is required or expected to be required for funding
(3) ❑ Other (please specify) _____

Has or will this research be submitted to a research ethics committee other than the Research Ethics Committee at SDU?

(1) ❑ No
(3) ❑ Yes

Please describe the status of the application submitted to a research ethics committee other than the Research Ethics Committee at SDU.
Please provide the name of the committee, date of submission, and contact person's name and contact details (if known).

_____

Danish, lay person description of the research project

Background and context

Please describe in very broad terms what the project is about and why it is relevant (max 100 words).

_____

Aims

Please provide a brief description of the aims of the study (max 50 words)

_____

Design and methodology

Please outline the experimental design and/or methodology of the study, including description of any invasive or intrusive procedures, if applicable (max 100 words).

_____

Research including human participants

Does your research activity involve human participants?

(9) ❑ Yes
(10) ❑ No

Please specify the type of human participants that are involved in your research activity

(1) ❑ Volunteers for e.g. social, technical or human sciences studies
(2) ❑ Patients for medical studies
(3) ❑ Healthy volunteers for medical studies
(4) ❑ Potentially vulnerable individuals or groups
(5) ❑ Children/minors
(6) ❑ Persons unable to give informed consent
(7) ❑ Other, please specify _____

Please describe your participant pool, e.g. age, gender, number of participants needed, inclusion and exclusion criteria

_____

Please describe how you intend to recruit and distribute your participants, e.g. selection and recruitment process, number of treatment or experimental groups

_____

Please describe what the participants be asked to do

_____

Please describe your data collection methods

_____

Will you obtain informed consent from the participants?

(9) ❑ Yes
(10) ❑ No

Will material or financial inducements be offered to participants (e.g. vouchers, cash, valuable items etc.)?

(9) ❑ Yes
(10) ❑ No

Please describe your procedures for obtaining informed consent from the participants

_____

Please explain your reasons not to obtain informed consent from the participants

_____

Please give details about the material or financial inducements that will be offered to participants (e.g. vouchers, cash, valuable items etc.).
Please include information about the amount of money (or equivalent) the participants receive.

_____

Do you inform participants that tax regulations may apply to financial compensations earned in your experiment?

(1) ❑ Yes
(2) ❑ No

Risk and harm

Will it be necessary for participants to take part in the study without their knowledge and consent at the time? For instance, this could be covert observation of people in non-public places.

(1) ❑ Yes
(2) ❑ No

Will the study involve discussion of sensitive topics? This could be for instance sexual activity, drug use, politics, mental health and other health conditions, religion.

(1) ❑ Yes
(2) ❑ No

Are drugs, placebos or other substances (i.e. food substances, vitamins) to be administered to the participants, or will the study involve invasive, intrusive or potentially harmful procedures?

(1) ❑ Yes
(2) ❑ No

Will tissue samples (including blood) be obtained from participants?

(1) ❑ Yes
(2) ❑ No

Is pain of more than mild discomfort likely to result from the study?

(1) ❑ Yes
(2) ❑ No

Could the study induce psychological stress, discomfort, anxiety in the participants, or cause harm or negative consequences?

(1) ❑ Yes
(2) ❑ No

Will the study involve prolonged and/or repetitive testing?

(1) ❑ Yes
(2) ❑ No

Is there a possibility that the safety of the researcher may be in question? (E.g. research in conflict zones)

(1) ❑ Yes
(2) ❑ No

Does the study involve participants who are particularly vulnerable? (E.g. hospital patients, patients with mental disorders, people with cognitive impairments, people receiving counseling, elderly people, self-help group members, refugees, paperless persons)

(1) ❑ Yes
(2) ❑ No

Does the study involve participants under the age of 18 or participants who are over 18 but unable to give informed consent? For instance children or people with learning disabilities.

(1) ❑ Yes
(2) ❑ No

Will the research involve investigation of illegal conduct or criminal offences?

(1) ❑ Yes
(2) ❑ No

You have stated that it will be necessary for participants to take part in the study without their knowledge and consent at the time.
Please describe your debriefing procedure, as well as how you plan to ensure that the deception will not have any negative affect on the participants' wellbeing.

_____

Data protection and management

Does your research project involve processing of personal data?

(1) ❑ Yes
(2) ❑ No

Will you be using registry data?

(1) ❑ Yes
(2) ❑ No

Did you contact SDU's Research Data Management Support regarding a Data Management Plan (DMP)?
For more information, please see https://www.sdu.dk/en/bibliotek/forskere/rdm+support

(1) ❑ Yes
(2) ❑ No

Please describe the kind of registry data you will be using

_____

Did you contact SDU RIO to apply for clearance regarding GDPR-issues?
RIO should be contacted via sdu.persondata@sdu.dk

(1) ❑ Yes
(2) ❑ No

Do you see any challenges for your project to fulfill SDU's requirements regarding GDPR?
If you do, please elaborate in your project description. Also, please also take into consideration how you will protect the participants' personal data.

(1) ❑ Yes
(2) ❑ No

International research

Will research activities take place outside Denmark?

(2) ❑ No
(1) ❑ Yes, but only within EU/EFTA
(3) ❑ Yes, including countries outside EU/EFTA

Please list the countries where research activities will take place.

_____

Please describe the research activities that take place outside EU/EFTA, including a description of any ethics issues, risks and benefits associated with the activities.

_____

Please describe any local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.) you plan to use.

_____

Please describe any material you plan to import from non-EU/non-EFTA-countries into Denmark. Please detail the type of material, and from what country it is imported.

_____

Please describe any material you plan to export from Denmark into non-EU/non-EFTA-countries. Please detail the type of material, and to what country it is exported.

_____

Does your research fall under the scope of the Nagoya Protocol on Access and Benefit-sharing (as described here: https://www.cbd.int/abs/), If yes, please elaborate in your project description.

(9) ❑ Yes
(10) ❑ No

Could the situation in the country put the individuals taking part in the research at risk?

(1) ❑ Yes
(2) ❑ No

Please describe the risk, and the details of the safety measures you intend to take, including training for staff and insurance cover.

_____

Environment, health, and safety

Does your research involve the use of elements that may cause harm to humans, including research staff, and/or to the environment, to animals or plants?

(9) ❑ Yes
(10) ❑ No

Does your research deal with endangered fauna and/or flora and/or protected areas?

(9) ❑ Yes
(10) ❑ No

Do you work in a classified laboratory?

(9) ❑ Yes
(10) ❑ No

Please describe the elements used and the harm it may cause humans, including research staff, and/or to the environment, to animals or plants.

_____

Please describe if you have familiarized yourself with any requirements that applies to research that involves risk for humans, environment, animals, plants, and whether your research complies with these requirements.

_____

Please list the endangered fauna and/or flora and/or protected areas that your research deals with.

_____

Please provide the name and contact info of the Head of classified laboratory you work in.

_____

Dual use, technological evolution, and use of artificial intelligence

Dual use: Can your research be misused, for instance for military purposes?

(9) ❑ Yes
(10) ❑ No

Can your research create or trigger technological developments that may have negative or positive impact on individuals or society?

This applies especially but not exclusively to human-machine-interaction, Artificial Intelligence and the like.

(9) ❑ Yes
(10) ❑ No

Does your research involve the development, deployment and/or use of Artificial Intelligence?

(9) ❑ Yes
(10) ❑ No

Please describe how your research could be misused. This should include risk assessment, details of the applicable legal requirements, and details of the measures to prevent misuse.

_____

Please describe how your research can create or trigger technological developments that may have negative or positive impact on individuals or society. This should include risk assessment and details of the measures to prevent negative impact.

_____

Please elaborate on your research's use of artificial intelligence. This should include answers to the following questions: Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)? Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?

_____

Ethical self-reflection

Please describe the potential ethical issues that you see in your project, and how you can solve them.
In general, research ethics issues could include, but is not limited to questions like: Could participants feel stressed by participating in the project? How would you handle incidental findings? Do you have to deceive the participants to some extent in order to check your hypotheses, and if so, what is your debriefing procedure afterwards? Issues related to GDPR, informed consent, use of digital labor platforms such as MTurk or Prolific, dual use, funding, psychological trigger questions...