Ethical Approval for SDU Research Projects

The application consists of **A) the Research Description** and **B) the Ethics Checklist** covering six areas of potential ethical concern. When applying for review by the REC, all sections need to be completed for research projects at the University of Southern Denmark prior to data collection.

The seven topics of the ethics checklist are as follows:

1. Research including Human Participants (including GDPR)
2. Research including Animals
3. Research including non-EU-/EFTA-member states
4. Environment and Health & Safety
5. Technological Evolution
6. Accidental Findings
7. Other Ethics Issues

The documents are reviewed by SDU’s Research Ethics Committee (REC) in order to determine:

1. The risk or harm that the project may cause for participants/animals
2. The risk or harm that the project may cause for environment and society
3. Whether further ethical approval is needed by a third party.

Please note that any changes in the study’s design and conduct during the study that have an impact of ethical aspects must be notified to the REC, as this may require submitting a new Research Approval application.

Please refer to the general principles for conducting research before submitting these documents.   
**In case of unclarities regarding the vocabulary used, please refer to the glossary.**

Further information will be available online.  
  
As for the documents requested in the questionnaire, provide those you have already available and describe how you will proceed with those still missing.

**General notes:**

* The REC issues its approval under the condition that all other approvals from the other relevant institutions are granted.
* Student projects have to be reviewed by their supervisors. Students noticing anything that may raise ethical concerns must address this with their supervisors.
* The approval issued in this process refers to the project description submitted with this application. If changes in the project setup are made that result in questions previously answered with “no”, to be answered with “yes” after said alteration, the project has to undergo the review process anew.

Research Ethics Committee Application

**University of Southern Denmark**

A. Research Description

|  |  |  |  |
| --- | --- | --- | --- |
| Applicant details | | | |
| *Please answer each question by typing in the column to the right.* | | | |
| For Researchers |  | | |
| Principal Investigator’s name |  | | |
| Project Collaborator(s)/Co-Investigator(s) Name(s) |  | | |
| Department or Research Group |  | | |
| Email |  | | |
| Telephone |  | | |
| Project Details | | | |
| Project title |  | | |
| Estimated date for starting and ending data collection |  | | |
| Source of funding (if any).  *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.* |  | | |
|  | | | |
| To evaluate if the SDU REC is responsible to review this project: Health Science Projects | Yes | No |  |
| Does your research involve invasive experiments on live-born human subjects, human sex cells intended for fertilization, human fertilized eggs, fetuses and fetuses, tissues, cells and hereditary components of human, fetuses and the like, or deceased?  This includes clinical trials of medicinal products in humans and clinical trials of medical devices. |  |  |  |
|  | * **If yes: Please apply at *Regionale Videnskabsetiske Komiteer*! You do not have to proceed with this questionnaire!** | | |
|  |  | | |
| Other Information | Yes | No | If yes, provide the following details: |
| Has or will this research be submitted to a research ethics committee other than the Research Ethics Committee at SDU? |  |  | * *Name of committee:* * *Date of submission:* * *Contact person’s name and contact details (if known):* |
|  | | | |
| Research Description | | | |
| Question | Answer | | |
| Study Description | | | |
| Provide a description of the background of the study with references to relevant literature (max. 100 words). |  | | |
| Provide a brief description of the aims of the study. |  | | |
| Outline the design and methodology of the study and details of any invasive or intrusive procedures, if applicable.  Include a brief description of the experimental design and setup (max. 100 words) and attach/upload the developed tools such as questionnaires, interview guides etc. |  | | |

B. Ethics Checklist

*Please answer each question by ticking the appropriate box. If ‘Yes’, give brief details in the ‘Yes’ answer box.*

**If you foresee any ethics issues in your project other than the ones asked for in the sub-chapters of this questionnaire, please elaborate under point 6!**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Research including Human Participants | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| 1.0 Will your research include research with human participants? | |  |  | Confirm that Informed Consent will be obtained. | Templates of the Informed Consent forms + Information Sheets |
| * If yes, continue with the subsequent questions.   If not, proceed to the next topic. | | | |  | |
|  | | | | | |
| 1.1 Participant Pool | | | | | |
| If your research involves human participants: | |  | | | |
| * + 1. Who will be your participants? (E.g. age, gender, number of participants needed) | |  | | | |
| * + 1. How do you intend to recruit and distribute your participants? (E.g. selection and recruitment process, number of treatment groups) | |  | | | |
| * + 1. What will the participants be asked to do? | |  | | | |
| * + 1. How do you plan to attain informed consent? | |  | | | |
| * + 1. Which tools/methods will be used to collect participant data? | |  | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * + 1. Are your human participants volunteers for social or human science research? | |  |  | Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. |  |
| * + 1. Are they patients? | |  |  | 1. What disease/condition /disability do they have? 2. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3. What is your policy on incidental findings? |  |
| * + 1. Are they healthy volunteers for medical studies? | |  |  |  |  |
|  | | | | | |
| * 1. Risk and Harm | | Yes | No |  | |
| * + 1. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (E.g. covert observation of people in non-public places) | |  |  | * If you enter “yes” in any of these boxes, elaborate in your project description. | |
| * + 1. Will the study involve actively deceiving the participants? (E.g., will participants be informed deliberately falsely, will information be withheld from them, or will they be misled in such a way that they are likely to object or show unease when debriefed about the study) | |  |  |
| * + 1. Will the study involve discussion of sensitive topics? (E.g. sexual activity, drug use, politics, mental health and other health conditions, religion) | |  |  |
| * + 1. 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. Will tissue samples (including blood) be obtained from participants? | |  |  |
| * + 1. Is pain or more than mild discomfort likely to result from the study? | |  |  |
| * + 1. Could the study induce psychological stress, discomfort, anxiety in the participants, or cause harm or negative consequences? | |  |  |
| * + 1. Will the study involve prolonged or repetitive testing? | |  |  |
| * + 1. Is there a possibility that the safety of the researcher may be in question? (E.g. research in conflict zones) | |  |  |
|  | | | | | |
| * 1. Participants and Confidentiality | | Yes | No |  | |
| * + 1. 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) | |  |  | * If you enter “yes” in any of these boxes, elaborate in your project description. | |
| * + 1. Does the study involve participants under the age of 18 or over who are unable to give informed consent? (E.g. children or people with learning disabilities) | |  |  |
| * + 1. Will the research involve investigation of illegal conduct or criminal offences? | |  |  |
|  | | | | | |
| * 1. Protection of Personal Data (GDPR) | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * 1. **Does your research involve processing of personal data?** | |  |  |  | |
| * If yes, continue with the subsequent questions.   If not, proceed to the next topic. | | | |  | |
| * + 1. **Did you apply for clearance regarding GDPR-issues?** | |  |  |  | Copy of said application, or approval issued by SDU RIO, whichever applicable |
| * **If not, please contact the person in charge for GDPR-issues at SDU RIO!** | | | |  | |
| * + 1. **Do you see any challenges for your project to fulfill SDU’s requirements regarding GDPR?** | |  |  | * If “yes”, elaborate in your project description. | |
|  | | | | | |
| * 1. Material Incentives | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * + 1. Will material or financial inducements be offered to participants? (e.g. vouchers, cash, valuable items etc.) | |  |  | * If “yes”, elaborate in your project description. * Also include which amount of money the participants receive. | |
| * + 1. Do you inform the participants that tax regulations may apply to financial compensations earned in your experiment? | |  |  |  | Templates of the Information Sheets |
|  | | | | | |
| 1. Research including Animals | | | | | |
|  | | Yes | No |  | |
| **2.0 Does your research involve animals?** | |  |  | * If “yes”, elaborate in your project description. | |
|  | | * **If yes: Please apply at the *Dyreforsøgstilsynet*!** | | | |
|  | | | | | |
| 1. Research including Non-EU-/EFTA-Member States | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * 1. **Are third (non-EU/EFTA) countries involved in your research?** | |  |  | List countries involved |  |
| * If yes, continue with the subsequent questions.   If not, proceed to the next topic. | | | |  | |
|  | | | | | |
| * 1. Will the research take place outside Denmark? | |  |  | List countries involved |  |
| * 1. Do the research related activities undertaken in the third (EU and/or non-EU/EFTA) countries raise potential ethics issues?  Specify the countries involved: | |  |  | 1. Risk-benefit analysis. 2. What activities are carried out in non-EU countries? Give details | 1. E.g. copies of ethics approvals and other authorizations or notifications (if required). 2. Confirmation that the activity could have been legally carried out in an EU country (for instance, an opinion from an appropriate ethics structure in an EU country). |
| * 1. Is it planned to use 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.)? | |  |  | What type of local resources will be used and how exactly?  Give details | * For human resources:   copies of ethics approvals (if available).   * For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the *UN Convention on Biological Diversity* (e.g. access permit and benefit sharing agreement). |
| * 1. Is it planned to import any material from non-EU/non-EFTA-countries into Denmark?   *(For data imports, see the corresponding section on GDPR)* | |  |  | Details of the type of materials to be imported. From where? Give details. | Copies of import licenses |
| * 1. Is it planned to export any material from Denmark to non-EU/non-EFTA-countries?   *(For data exports, see the corresponding requirements on GDPR)* | |  |  | Details of the type of materials to be exported.  To which country/countries? | Copies of export licenses |
| * 1. Could the situation in the country put the individuals taking part in the research at risk? | |  |  | Details of the safety measures you intend to take, including training for staff and insurance cover. |  |
|  | | | | | |
| 1. Environment and Health & Safety | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| 1. **Does your research involve the use of elements that may cause harm to the environment, to animals or plants? (For research involving animal experiments, see the corresponding section.)** | |  |  | List these elements |  |
| * If yes, continue with the subsequent questions.   If not, proceed to the next topic. | | | |  | |
| * 1. Have you familiarized yourself with the relevant requirements? | |  |  |  |  |
| 4.1.1 Does your research comply with the relevant requirements? | |  |  | Documentation requested by your faculty | Authorization papers issued by your faculty or the relevant authority |
| 4.2 Do you work in a classified laboratory? | |  |  | Name and contact info of the Head of Laboratory |  |
| * 1. Does your research deal with endangered fauna and/or flora and/or protected areas? | |  |  | List fauna/flora/area(s) | Specific authorizations (if required). |
| * 1. Does your research involve the use of elements that may cause harm to humans, including research staff? *(For research involving human participants, see the corresponding section.)* | |  |  | Details of the health & safety procedures | Safety classification of laboratory. |
|  | | | | | |
| 1. Technological Evolution | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * 1. 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. | |  |  | Please explain in your project description. |  |
|  | |  |  |  |  |
| 1. Accidental Findings [Dual Use] | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * 1. Can your research be misused and what is done to minimize those risks? | |  |  | Please explain in your project description: 1) Risk-assessment.  2) Details of the applicable legal requirements.  3) Details of the measures to prevent misuse. | 1. Copies of authorizations (if required). 2. Copies of security clearances (if applicable). 3. Copies of ethics approvals (if applicable). |
|  | | | | | |
| 1. Other Ethical Issues | | | | | |
|  | | Yes | No | If yes: Information to be provided | Documents to be provided/kept on file |
| * 1. Are there any other ethics issues that should be taken into consideration?   Please specify: | |  |  | Any information deemed relevant. | Any document deemed relevant. |
|  | | | | | |
| Signature | | | | | |
| *If this document is completed electronically contact details are required instead of signature.* | | | | | |
| Signature or contact details: | Date: | | |  |  |