## APPLICATION FOR ETHICS APPROVAL

*No ethics-relevant action should be taken until this application has been approved.*

*Please*

1. *first read the* [*Guidelines*](https://uniluxembourg.sharepoint.com/sites/ERP/Useful%20documents/Forms/AllItems.aspx?id=%2Fsites%2FERP%2FUseful%20documents%2FApplication%20Form%5FGuidelines%20%28ERP%2C%202025%29%2Epdf&parent=%2Fsites%2FERP%2FUseful%20documents) *to determine whether approval is required,*
2. *fill out this form following the instructions in the* [*Guidelines,*](https://uniluxembourg.sharepoint.com/sites/ERP/Useful%20documents/Forms/AllItems.aspx?id=%2Fsites%2FERP%2FUseful%20documents%2FApplication%20Form%5FGuidelines%20%28ERP%2C%202025%29%2Epdf&parent=%2Fsites%2FERP%2FUseful%20documents)
3. *add any additional information in separate files, and*
4. *send the complete application to* *erp-submissions@uni.lu**.*

**SECTION 1: PROJECT**

|  |  |
| --- | --- |
| Title: | *50 words max.* |
| Acronym: | *20 characters max.* |

**Applicant(s):**

|  |  |  |
| --- | --- | --- |
| **Researcher/Student** | Name: |  |
| Position at UL: | *doctoral candidate, post-doc, …* |
| Faculty / IC: | *FSTC, FDEF, or FLSHASE* |
| Research Unit: |  |
| Telephone no: | *(+352) 46 66 44 xxxx* |
| Email: | *name.surname@uni.lu* |

|  |  |  |
| --- | --- | --- |
| **Principal Investigator [[1]](#footnote-1)** | Name: |  |
| Position at UL: | *professor, post-doc, …* |
| Faculty / IC: | *FSTC, FDEF, or FLSHASE* |
| Research Unit: |  |
| Telephone no: | *(+352) 46 66 44 xxxx* |
| Email: | *name.surname@uni.lu*  |

*Please specify in case you are not employed at UL.*

*Please expand if more than 2 persons are involved.*

**Funding:**

|  |  |
| --- | --- |
| Source: | *FNR, ERC, UL, …* |
| Is ethical approval required before the funds can be obtained? | [ ]  Yes | [ ]  No |
|  |  |  |
| **Ethical approval** is being requested for:*Please note that enough detail needs to be provided for each study.* | [ ]  a single  study | [ ]  multiple studies |
| Has ethics approval already been obtained from another ethics committee for this project? | [ ]  Yes  | [ ]  No |
|  |  |  |
| Has ethics approval already been obtained from the ERP for a similar research design?  | [ ]  Yes  | [ ]  No |

In case ethics approval has already been obtained, please provide references.

(see points below)

* …the reference number of the ERP.
* …from another ethics committee, please join a copy of the approval letter.
* …

###### Please list any research area-specific ethics guidelines (with a link to the relevant document) you have used in the planning of your research (*e.g.* from a professional society).

* *…*
* *…*

**SECTION 2: SHORT SUMMARY OF THE PROJECT**

(including research design and methodology)

*300 words max.*

###### SECTION 3: PROPOSED START DATE AND DURATION OF ETHICS-RELEVANT ACTIVITY FOR EACH STUDY IN THE PROJECT

Please see the [Guidelines](https://uniluxembourg.sharepoint.com/%3Ab%3A/r/sites/ERP/Useful%20documents/Application%20Form_Guidelines%20%28ERP%2C%202025%29.pdf?csf=1&web=1&e=Mo2gg1) for the definition of **ethics-relevant** activities.

|  |  |  |  |
| --- | --- | --- | --- |
| **Study No.** | **Study Title** | **Start Date** | **Duration in Months** |
| **1.** | *50 words max.* |  |  |
| **2.** | *50 words max.* |  |  |

*Please expand the rows in case of additional studies.*

**SECTION 4: AIM OF EACH OF THE STUDIES**

|  |  |  |
| --- | --- | --- |
| **Study No.** | **Aim**  | **Study will involve:***Please tick all appropriate boxes* |
| **1.** | *100 words max.* | [ ]  Human participants [ ]  Vulnerable population [[2]](#footnote-2) [ ]  Human biological material [ ]  Pre-collected biological material[ ]  Personal data [ ]  Pre-collected personal data[ ]  risks on the environment [ ]  risks on the society |
| **2.** | *100 words max.* | [ ]  Human participants [ ]  Vulnerable population[ ]  Human biological material [ ]  Pre-collected biological material[ ]  Personal data [ ]  Pre-collected personal data[ ]  risks on the environment [ ]  risks on the society |

*Please expand the rows in case of additional studies.*

**SECTION 5: DETAILS OF EACH STUDY**

Please specify the ethically relevant issues for each of the studies.

|  |  |  |
| --- | --- | --- |
| **Study 1**  | Target sample size:(Please justify the target sample size, either statistically or by referring to existing literature) |  |
| Key inclusion criteria: |  |
| Key exclusion criteria: |  |
| Age range of participants: |  |
| Country/ies of recruitment: |  |
| Expected duration of procedure[[3]](#footnote-3): |  |
| Data Collection:  | *Audio / Video* |
| Methodology: | *Please explain concisely, 750 words max.*  |

*Please expand the table in case of additional studies.*

**SECTION 6:** **RISK ASSESSMENT AND RISK MINIMIZATION**

*A risk assessment should be carried out for each study and it should be demonstrated that appropriate measures are taken to minimize any reasonably foreseeable risk, discomfort or disadvantages.*

**6.1- Health and safety risk(s) for the HUMAN PARTICIPANTS involved**

|  |  |  |
| --- | --- | --- |
|  | ***Potential risk(s)*** | ***Extent of risk(s) and measures taken*** |
| **Study 1** | Human participants are involved in the study with potential risk related to [ ]  Physical harm[ ]  Psychological harm [ ]  Invasion of privacy[ ]  Social and economic harm[ ]  Other | *Please explain concisely, 750 words max.*  |
| Are there any specific risks to the human participants involved, if any. | *Please explain concisely.* |

*Please expand the table in case of additional studies.*

**6.2- Health and safety risk(s) for the RESEARCHER(S)**

|  |  |  |
| --- | --- | --- |
|  | ***Potential risk(s)*** | ***Extent of risk(s) and measures taken*** |
| **Study 1** | Where does the research take place?[ ]  Premises of UL[ ]  Public area[ ]  Study participant’s home[ ]  Other location*Please provide a copy of any authorisation / permission needed with regard to the research location.* | *Please explain concisely, 750 words max.*  |
| Are there any specific risks to the researchers (which are not covered by the location)? | *Please explain concisely.* |

*Please expand the table in case of additional studies.*

**6.3- Changes to the ENVIRONMENT and SOCIETY**

|  |  |  |
| --- | --- | --- |
|  | ***Potential risk(s)*** | ***Extent of risk(s) and measures taken*** |
| **Study 1** | Research activity includes [ ]  Pollutants [ ]  Chemical or biological waste [ ]  Dual use research of concern (*e.g.* military research purpose(s)) [ ]  Other | *Please explain concisely, 750 words max.*  |
| Are there any specific risks to the environment and/or society? | *Please explain concisely.* |

*Please expand the table in case of additional studies.*

**SECTION 7: PARTICIPANTS’ INFORMATION AND CONSENT**

Participants (or their legal representatives) have to be provided with information on the study, and participants have to give their consent.

*Consent form template and instructions can be found on the* [*University internet site*](https://www.uni.lu/en/about/organisation/administration/ethics-review-panel/)*.*

Please indicate which information and consent form(s) you will use for your study/studies and attach a version of all information (in the language(s) used in the study) given to the participants (or their legal representatives) to this application:

[ ]  Participants’ **information sheet**(s) for study/studies ………

Please tick as appropriate: [ ]  Human participants

[ ]  Vulnerable population

[ ]  Participants’ **consent** for study/studies ………

Please tick as appropriate: [ ]  Human participants

[ ]  Vulnerable population

|  |  |  |
| --- | --- | --- |
| Have you planned an additional **oral debriefing**? | [ ]  Yes | [ ]  No |
| Have you made explicitly clear that participants **voluntarily** take part in the study? | [ ]  Yes  | [ ]  No |
| Have you made clear that participants can **withdraw** from the study at any time without consequences? | [ ]  Yes  | [ ]  No |
| Do you plan to do **audio/video recording?**If you do **audio/video recording,** did you include this in the informed consent? | [ ]  Yes [ ]  Yes  | [ ]  No[ ]  No |
| Have you informed participants on the processing and management of **personal data** in the consent form?Do you have the intention to use the data for further research?Do you use the informed consent for a single study purpose? | [ ]  Yes [ ]  Yes[ ]  Yes | [ ]  No[ ]  No[ ]  No |
| Have you addressed how **unexpected findings** will be handled?*Unexpected findings are those which may reveal situations that suggest the presence of a problem. If you have such eventuality, specify how you intend to handle the situation.* | [ ]  Yes | [ ]  No[ ]  N/A |
| Have you mentioned to provide the study participant with a **copy** of the consent? | [ ]  Yes | [ ]  No |

**SECTION 8: DATA PROTECTION**

**8.1- Anonymity / Pseudonymity**

*Please describe for each of the studies, how anonymity or pseudonymity is addressed [[4]](#footnote-4).*

*Please explain concisely, 750 words max.*

|  |  |  |
| --- | --- | --- |
| I am aware of and I comply with the University’s data protection regulations.<https://wwwen.uni.lu/university/data_protection/data_protection_policy_and_faq>. | [ ]  Yes | [ ]  No |

Article 38, related to the position of the DPO of the GDPR and the UL Data Protection Regulation set out the data protection policy of the University.

Further details can be found under: <https://uniluxembourg.sharepoint.com/sites/dpo/SitePages/Data-Protection-Office.aspx>

In addition to the GDPR regulations, the ERP needs to be informed about pseudonymity – anonymity, data storage and data access (see the following sections).

**8.2- Data storage**

*Please fill in the information in the following table on provisions for integrity and confidentiality.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *Raw data**(incl. video or audio recordings)* | *Processed data**(anonymized, pseudonymized)* | *Document(s) containing the names, contact information and personal details (the pseudonymisation key list)* | *Other material* |
| Data carrier(digitalized or paper form) |  |  |  |  |
| Number of copies | *e.g. 1 copy with researcher, 1 copy with supervisor* |  |  |  |
| Storage Location | *e.g. UL server, laptop* |  |  |  |
| Retention period | *e.g. 10 years* |  |  |  |

**8.3- Data access**

How is access being controlled (physical access, security)?

* *Please list the people who have access to the different types of data under 8.2 – Data storage.*
* *Is cryptography used for managing data access?*
* *…*

**ADDITIONAL DOCUMENTS:**

The following document(s) has/ have been attached:

|  |  |
| --- | --- |
| [ ]  | Previous ethics approvals for the study/studies (a copy of the approval letter, a description of any modifications made to the approved research design) |
| [ ]  | A version of all material used to recruit participants (*e.g.* flyers, letters). |
| [ ]  | A brief description of equipment used, if relevant. |
| [ ]  | Information sheet(s) for participants, legal guardians and/or other involved parties |
| [ ]  | Consent form(s) for participants, legal guardians and other involved parties |
| [ ]  | A version of all study materials given to the participants (*e.g.* questionnaires, assignments) |
| [ ]  | A copy of any other information given to the participants |
| [ ]  | Any additional document(s), please specify …………………………………………………. |

*Please provide the documents in all* ***languages used*** *in the study.*

**DECLARATION:**

|  |
| --- |
| We confirm to conduct the research in an ethically appropriate way in accordance with the University of Luxembourg [*Policy on Ethics in Research*.](https://uniluxembourg.sharepoint.com/sites/ERP/Style%20Library/Images/ERP/Pages/Useful-Documents/University%20of%20Luxembourg%20Policy%20on%20Ethics%20in%20Research%20CU%20approved%2013.10.2010.pdf) |

|  |  |  |
| --- | --- | --- |
| **Researcher** | Name: |  |
| Signature:(hand-signed) |  |
| Date: |  |

|  |  |  |
| --- | --- | --- |
| **Principal Investigator** | Name: |  |
| Signature:(hand-signed) |  |
| Date: |  |

*Please expand the rows in case of additional researcher(s) and/or PI(s).*

1. if different from researcher; Supervisor if the researcher is a PhD student [↑](#footnote-ref-1)
2. Vulnerable populations include pregnant women, neonates, children and adolescents, individuals with cognitive impairment and/or mental disorders, people with anxieties, mentally-deficient persons, members of social minorities, the elderly, and detained persons. *Please consult also page 38 of the Research Ethics Guidelines.* [↑](#footnote-ref-2)
3. Please indicate the duration the data collection procedure (e.g. 30 min), not of the whole project [↑](#footnote-ref-3)
4. Pseudonymization is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject.

Data anonymization is the process of irreversible transformation of personal data. [↑](#footnote-ref-4)