Application for Ethics Review by the Research Ethics Committee

Basic project information:

Project title:

(Title in Czech)

(Title in English – mandatory for obtaining approval in English)

Principal investigator: Click here and enter text.

Investigating institution:

(Enter the full MU faculty name)

Co-investigating institution:

(Enter the co-investigating institution at MU and/or institutions/organizations outside MU.)

Collaborating institutions:

(Enter the collaborating institutions/organizations outside MU – they are not official co-investigators of the project – collaboration based on for example "Letter of commitment".)

Project period: (month and year suffice)

Funding source:

(State the grant provider, e.g. grant agency (GAČR, TAČR, GAMU) or MŠMT (Ministry of Youth, Education, and Sport), MZ (Ministry of Health), MV (Ministry of the Interior), foundation, potentially "MU internal project", "thesis", "dissertation".)

The investigator is responsible for providing accurate and complete data in the application as well as for their compliance with the wording of the project proposal submitted to the grant provider.

Instructions:

This application (version dated: v200226) can be updated on a continuous basis.

The current version of the application can be downloaded here: https://is.muni.cz/auth/do/rect/metodika/VaV/vyzkum/etika/

The application specifies all project information (points 1 to 6) and other documents that must be submitted to assess the ethical aspects of the projects. The Project Participation Agreement / Informed Consent must be submitted together with the application.

If the required information is irrelevant for your project, please enter "x". Do not remove any texts in the application.

You can use Czech or English to complete the application.

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Research project description:

1. **Project rationale: project goals, research justification, specifying the project benefits/outcomes:**

Click here to enter text

2. **Methodological approaches of the project:**

Click here to enter text

3. **Detailed description of research aspects relevant to research ethics:**

a) Human biological material

- *If human biological material will be used during the proposed research,* ***state what kind of material it is*** *– e.g. blood, urine, certain tissue, etc. (in case the project will be solved using only commercially available biological material, e.g. cell lines, REC approval is not needed.)*
- *Describe* ***from whom, where, and under what conditions*** *the research material* ***will be obtained.***

Click here to enter text

Note: *It is necessary to provide* ***Project Participation Agreement / Informed Consent including consent to the use of the collected material for the research purposes of the project or for research purposes in general*** *(if the consent is granted to a different institution than Masaryk University, it is necessary to provide the approval of this consent form by the ethics committee of the particular institution).*

b) Human subject

- ***Describe the participants*** *or groups of participants (healthy volunteers / patients, adults / minors / children, seniors, etc.) including* ***the size of the research sample*** */ research samples.*

  State the ***inclusion and exclusion criteria*** *for selecting the research participants and specify all the conditions of their participation.*

Click here to enter text

- *Describe* ***the nature, scope, and the duration of planned procedures*** in which the human subject will participate: what and at what time will happen to the participant, if or how often the procedures will be repeated, etc.

*Describe **how/from where the research data will be obtained** (e.g. own measurement on research participants, data from medical records, questionnaires, etc.).*

*Provide **details of any necessary stress/burden and limitations of participants** necessary for participating in the research.*

Click here to enter text

- *Describe **the method of recruiting participants for research:** who will reach out to participants (researcher / trained representative / attending physician / advertising, etc.), how and where the participants will be addressed.*

Click here to enter text.

***Note**: It is necessary to **provide a Project Participation Agreement / Informed Consent** including consenting to the processing of personal data if any data is collected – use the form provided by MU Research Ethics Committee. If informed consent is granted to a different institution than Masaryk University, it is necessary to provide the approval of this consent form by the ethics committee of the particular institution.*

c) Participation of persons unable to give informed consent, vulnerable persons, and persons in dependent positions

- *If you plan to include persons incapable to give informed consent to participate in research or persons with reduced capacity to give informed consent to participate in research (e.g. minors, persons with mental illness, etc.), you need to specify in detail the methods of recruiting research participants and obtaining their informed consent.*
- *If you plan to include vulnerable persons (e.g. pregnant women, elderly people), you need to specify in detail the methods of recruiting research participants and obtaining their informed consent.*
- *If you plan to include persons in dependent positions (e.g. students of your courses or MU students in general, your subordinates), you need to specify in detail the methods of recruiting research participants and obtaining their informed consent.*

Click here to enter text

d) Risks

- *Describe all the risks (health, physical in general, mental, other) associated with the project that may pose threat to the research participants.*
- *If necessary, provide insurance details or other compensation measures in case the participants are harmed as a result of participating in the research.*

Click here to enter text

e) Possibility of participation withdrawal

- *Indicate the time restrictions and the requirements for the participants to withdraw from the research. (Withdrawing from the research makes sense only if the part of the research involving the given participant is still in progress and their data can be distinguished from the data of other participants – that is until the time of anonymisation. In most cases, it is ill-advised to make withdrawing available while the data obtained is being processed or even already published.)*

Click here to enter text

f) Deception research

- *If, due to the nature of the research, it is not possible to inform the participants of the true purpose of the research project (e.g. in behavioural studies), describe how the participants will be informed about the research.*
- *State if the research plans on using a false statement about its purpose (a cover story). If yes, please specify and provide the script that will be used by the researchers to explain the study.*
- *Explain when participants will be debriefed and who will debrief them. Provide copies of the debriefing statement that will be given to participants.*

Click here to enter text

g) Incidental findings

- *Describe the way the research addresses incidental (or unsolicited) findings or even foreseeable events which may be relevant to the health of the research participants – e.g. detecting abnormal values that may indicate a symptom of a disease or atypical/pathological findings detected by the used imaging methods.*
- *State if and how the participants are notified of the possibility of incidental findings and whether they can choose to be informed of these findings or not.*
- *In the case of using biomedical methods (e.g. magnetic resonance), indicate if the research participants are informed in advance that these are not used for examining their health condition, that the results are not assessed by a doctor, etc.*

Click here to enter text

h) Incentives for research participation

- *State if the participants are offered incentives for participating in the research (monetary or other).*

- *Enter the details related to monetary incentives (applicable conditions, legal basis, and payment disbursement)*

Click here to enter text

i) Cooperation with health facilities

- *In case the project includes working with patients, obtaining their biological material, or processing patient data, it is necessary to ensure adequate participation of the health facility during the research.*
- *Specify the conditions of the cooperation during the research.*

Click here to enter text

Note:

If the health facility is not the project co-investigator, this application also must include a confirmation of the cooperation from the given institution = health facility (a letter of commitment signed by the statutory representative of the institution)

In case the cooperating institution has its own ethics committee, it is recommended to have the research project approved by that committee as well – be aware that this approval does not replace the project approval granted by the MU REC (if MU is the principal investigator, the project must always be approved by MU REC and only this document is submitted as part of the grant application).

4. Data handling and personal data protection

If personal data are processed as part of the research, it is necessary to ensure compliance with the General Regulation on Personal Data Protection – EU 2016/679 (GDPR). ***Fill in the following even if you believe that you are not processing personal data!*** *(Note: personal data is any piece of information that could be used to identify a specific person; for example, audio/video recordings are always personal data)*

- ***State all data*** *of the* ***participants*** *that are gathered (such as name, date of birth, physiological parameters, demographic data, measurement results, questionnaire replies, audio/video recordings, contact data – email, telephone number, address):*

Click here to enter text

- ***Obtaining and processing data:*** *How are the participants' data obtained? Describe the method of collecting data, using pseudonymisation, or other method of protection. (For retrospective studies, provide Project Participation Agreement / Informed Consent that allows the processing the data. If this consent was granted to an institution other than Masaryk University, it is necessary to document the approval by the ethics committee of the particular institution.)*

Click here to enter text

- ***Data access:*** *Who will have access to the individual data and under what conditions?*

Click here to enter text

- ***Data storage:*** *Where will the data/personal information be stored? How will they be secured against unauthorised use, theft, loss, or misuse? (e.g. office, USB flash drive, computer (not) connected to the internet, internal storage of the investigator's department/ICS, external storage).*

Click here to enter text

- ***Storage time:*** *How long will the personal data be stored and when will they be deleted or anonymised? (e.g. storage for the period of data collection, for the duration of the project, for … years in contact details for the purpose of invitation to further research, for the duration the data and samples remain useful for research in the given field – on the basis of consent for the secondary use of data). NOTE: personal data can be stored only for the duration of the purpose for their processing. Once the purpose or reason for processing ends, it is necessary to delete personal data and store research data in an anonymised form.*

Click here to enter text

- ***Transfer of (personal) data to third parties:*** *Enter more details in case data are transferred outside MU; this includes additional specification of the data, guarantees of their protection, and their further handling.*

Click here to enter text

Note: *Please use the recommended template of informed consent and consent to data processing provided by the REC:* https://is.muni.cz/auth/do/rect/metodika/VaV/vyzkum/etika/

5. Further use of collected data and biological samples

- *State if the research plans the retention of the collected biological samples and personal data even after the end of the proposed research project (**secondary use**). If yes, please specify the conditions of further use. Please use the recommended wording in the text of the consent form for the applicant and always specify the area of the research in which the data is to be used. Differentiate between using pseudonymised research data (that is coded personal data which can be linked to a specific person) = you need the explicit consent of the participant, and using anonymised research data (research data are anonymised if the personal data are deleted and its subjects can no longer be identified in the research data) = you do not need explicit consent of the participant.*

Click here to enter text

6. Composition of the research team

- *Enter the names of all team members, including information on the institution that they represent in the project (especially if multiple institutions participate in the project).*

Click here to enter text