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Application for project assessment by the Ethics Committee of the Faculty of Medicine MU

Project background:

Project name:

Enter text.

Principal Investigator:

Enter text.

MU Organisational Unit (Provide the full name of the faculty and the department/lab):

Enter text.

Co-investigating institution (Specify MU department and/or institution/organisation outside MU.):

Enter text.

Collaborating institution (Indicate institutions/organizations outside MU - not official co-researchers of the project - cooperation e.g. on the basis of a "Letter of Commitment"):

Enter text.

Implementation period (month and year are sufficient):

Enter text.

Source of funding (Indicate the grant provider, e.g. grant agency (GAČR, TAČR), ministry (MŠMT, MZ, MV) or foundation. In the case of projects funded by Masaryk University, please indicate "MU" and the type of project ("GAMU", "IGA", "Specific Research", "Internal Project", "Thesis", "Dissertation", etc.):

Enter text.

The Principal Investigator is responsible for the truthful and complete completion of the data in the application and for their consistency with the text of the project proposal submitted to the grant provider.

Instructions:

Fill in all text fields. If the requested information is irrelevant to your project, enter "×".

Please do not remove any text.

The application can be filled in Czech or English.

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Description of the research project:

1. **<u>The objective of the project, justification of its solution and specification of the benefits of the project</u>:**

Click here and enter the text.

2. **<u>Methodological approaches used in the project</u>:**

Click here and enter the text.

3. **<u>Detailed description of ethically relevant aspects of the research:</u>**

3.1. Human biological material

3.1.1. *If human biological material will be used in the planned research, **specify what the material will be** - e.g. blood, urine, specific tissue, etc. This includes the use of retrospective samples. If the project will only use commercially available biological material, e.g. collection cell lines, approval by the MU Faculty of Medicine Ethics Committee (hereinafter referred to as "MU Faculty of Medicine Ethics Committee") is not required.*

3.1.2. *Describe **from whom, where and under what conditions the** material for the research **will/was obtained**.*

3.1.3. *Describe whether and what **additional data** will be obtained with the biological material samples (clinical, demographic, etc.)*

3.1.4. *Indicate when and by whom any **pseudonymisation of samples** will be carried out.*

3.1.5. *Indicate the institution that collected and provides the biological material (if relevant).*

***Please note**: It is necessary to provide a **template of informed consent, on the basis of which the collected material can be used for the project or for research purposes in general** (if this consent is/was granted to an institution other than Masaryk University, it is necessary to provide evidence of approval of this consent by the ethics committee of the institution).*

Click here and enter the text.

3.1.6. *Describe who (MU department, other institution), where and how the obtained biological material will be handled - who will **process and store it.***

3.1.7. *Indicate when and by whom any **remaining biological material** will be **disposed of**. If the material will be retained after the project has been completed, please describe the details in point 5 of this application.*

Click here and enter the text.

3.1.8. *In case the **biological material** will be **transferred to a third party** (e.g. for analysis), please indicate under which legal title (material transfer agreement, other contract, etc.) such transfer will take place.*

Click here and enter the text.

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3.2. Research participants

*3.2.1. Characterize the **participants** or groups of participants (healthy volunteers/patients, adults/youth/children/seniors, etc.), including an indication of **the size of the research population**(s).*

*3.2.2. Specify **inclusive and exclusive criteria for** the selection of research participants and specify any conditions for their participation.*

Click here and enter the text.

*3.2.3. Describe the **characteristic, range and duration of the planned procedures**: what will happen to the participant when, whether or how often the procedures will be repeated, etc.*

*3.2.4. Describe **how/where the research data will be collected** (e.g. self-measurements on research participants, data from medical records, questionnaires, etc.).*

*3.2.5. Please provide details of **any necessary burdens and constraints on participants in relation to** participation in the research.*

Click here and enter the text.

*3.2.6. Describe **how participants will be recruited for the research** (recruitment): who will approach participants (researcher/trained representative/treating physician/advertising, etc.), how and where participants will be approached.*

Click here and enter the text.

*3.2.7. Describe the **method and timing of providing consent to participate in the research** (especially when given outside of face-to-face contact, e.g. online, by phone, email)*

Click here and enter the text.

***Please note: A template of informed consent form for participation in the research,** including consent for processing of personal data if collected (you can use the ECV model), or patient consent given to the healthcare facility, is required. If the consent is given to an institution other than Masaryk University, it must be accompanied by the approval of that institution's ethics committee.*

3.3. Participation of persons unable to give consent, vulnerable persons and persons in a dependent position

***Detailed justification for the inclusion of** these groups of people **in the research** must be given if they are participating in the research:*

- ***Persons unable to consent to** participate in research, or persons with reduced capacity to consent (e.g. persons with mental illness, children),*
- ***Vulnerable persons** (e.g. pregnant women, children, adolescents, elderly, patients),*
- ***persons in a dependent position** (e.g. students in your courses or MU students in general, subordinates, patients)*

Click here and enter the text.

Please note: *In the case of participation of* ***minors*** *(children, adolescents), the following must be documented with regard to the specific circumstances of the research:*

- *the consent of the legal representative, if necessary supplemented*
  - *understandable information about the research for the minor*
  - *the minor's consent to research adapted to his or her intellectual abilities*

or

- *independent consent of the minor if the nature of the research and the minor's intellectual and voluntary capacities allow it (justification must be given)*

3.4. Risks

3.4.1. Describe any relevant risks (medical, physical in general, mental, other) that may be posed to research participants.

3.4.2. If relevant, please provide details of insurance or other compensation arrangements in the event of harm arising from participation in the research.

Click here and enter the text.

3.5. Option to withdraw from research

Indicate by when and under what conditions participants have the option to withdraw from the research. The right to withdraw cannot be denied, however, the option to withdraw from the research is only really meaningful as long as the data can be distinguished from others - i.e. until anonymisation. In most cases, it is not possible to allow withdrawal at the time when the collected data are being processed or even already published.

Click here and enter the text.

3.6. Research involving deception

3.6.1. If the nature of the research makes it impossible to tell participants the real aim of the research project (e.g. in behavioural studies), describe how participants will be informed about the research.

3.6.2. Indicate whether the research will use a fictional description of its purpose (cover story). If so, please specify what kind.

3.6.3. Describe when and how the debriefing will be conducted after the research is completed.

Click here and enter the text.

3.7. Incidental findings

Describe how situations will be handled when an incidental/unsolicited finding or even a predictable event occurs that may be important in relation to the health status of research participants - e.g. the detection of anomalous values that may be indicative of disease, or an atypical/pathological finding using imaging methods.

Click here and enter the text.

***Please note**: The possibility of incidental findings must be brought to the attention of the participants in the informed consent and **they must be given the opportunity to choose whether they wish to be informed** of such findings. In the case of the use of biomedical methods (e.g. MRI), participants must be informed in advance that this is not a health examination, that the results will not be evaluated by a physician, etc.*

3.8. Reward for participation in research

3.8.1. Indicate whether participants will be rewarded (financially or otherwise) for their participation in the research.

3.8.2. Please give details of any financial rewards: under what conditions, on what legal basis and how they will be paid.

Click here and enter the text.

***Please note**: If reward is paid on the basis of a contract, please provide the text of the contract. It is not possible to pay a reward on the basis of an agreement to complete a job (in Czech DPP). We recommend using the model contract here.*

3.9. Cooperation with health care facilities

3.9.1. If the project will involve working with patients, obtaining biological material from patients or working with patient data, it is necessary to ensure adequate participation of the healthcare facility in the research.

3.9.2. Specify the terms of the research collaboration.

Click here and enter the text.

Please note:

- *If the healthcare facility is not a co-investigator of the project, please provide a **letter** of **commitment** signed by the statutory representative of the health care facility. A template can be found here.*
- *In case the collaborating health care facility has its own ethics committee, provide the **approval of the project also by the ethics committee of the health care facility** - note that such approval does not replace the approval of the project by MU REC; if the principal investigator is Masaryk University, the project must always be approved by the MU REC and only this approval is attached as part of the project application submitted to the grant provider.*
- *If you plan to use patient data from the medical records, you must also provide **consent to access the medical records** with your application. This can be formulated separately or as part of an informed consent or consent to participate in research.*

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4. Data management and personal data protection

If personal data will be processed within the planned research, compliance with the General Data Protection Regulation - EU 2016/679 (GDPR) must be ensured. Note: personal data is any data that can be linked in any way to a specific person, e.g. audio/video recordings are always personal data. ***Please fill in the following even if you believe you are not processing personal data!***

4.1. Participants data

Provide all data that will be collected on participants (e.g. name, date of birth, physiological parameters, demographic data, measurement results, questionnaire responses, audio/video recordings, contact details - email, phone, address).

Click here and enter the text.

4.2. Data collection and processing

4.2.1. Describe the method of data collection - how data will be collected from/about participants.

4.2.2. Describe the process of pseudonymisation or other means of protecting personal data.

Click here and enter the text.

***Please note**: For retrospective studies, provide a model informed consent form to allow the use of the data. If this consent was granted to an institution other than Masaryk University, it must be documented that it was approved by the ethics committee of that institution.*

4.3. Access to data

4.3.1. Who will have access to the individual research data?

4.3.2. Who will have access to the encryption key, i.e. will be able to link the identity of the participant to the data obtained, and under what conditions?

Click here and enter the text.

4.4. Data storage

4.4.1. Where will be stored:

a) research data (e.g. questionnaire responses, recordings, measurement results, etc.),

b) personal data (encryption key, contact details, etc.)?

In the case of electronic data, please indicate the category of data and the chosen storage according to the ICT recommendations for the Usage of Storages. Identify where the encryption key will be stored and where other pseudonymised data will be stored (must be stored separately).

4.4.2. Describe the protection of data against unauthorised use, leakage, loss, misuse?

Enter text.

4.5. Storage period of personal data

Warning:

- *Data must be stored for the shortest time possible. Personal data may only be stored for as long as the purpose for which they are processed lasts. If the purpose or reason for processing ceases to exist, the personal data must be deleted and the research data must be stored only in anonymised form.*

- *According to MU Directive No.1/2018, the consent form for participation in research and processing of personal data must be kept for at least 5 years after the end of the processing of personal data.*

4.5.1 How long will the personal data be stored? When will the personal data be deleted = the research data will be anonymised?

Enter text.

4.6. Transfer of data to third parties

In the case of transfer of data outside Masaryk University, please provide the specification of the data, the recipient (institution, country), the reason for the transfer and, if applicable, the guarantees for their protection during further handling.

Enter text.

5. Secondary use of the data and biological material

Is it planned to keep the biological material or personal data (i.e. data enabling identification of the participant) after the end of the submitted research project for further use in certain areas of research? If yes, please specify the conditions of the further use. Always specify the research area in which such data are to be used.

Enter text.

Please note:

- *Further use of biological material or personal data in research must be properly justified.*
- *If the same purpose can be achieved with anonymous research data, there is no reason to keep it in pseudonymised form for secondary use.*
- *Distinguish between*
  - *a) the use of pseudonymised research data (i.e. the data stored under a code and can be linked with a specific person) = you need explicit consent from the participant and*
  - *b) the use of anonymous research data (i.e. the data has been anonymised and there is no way of linking it to a specific participant) = you do not need explicit consent from the participant.*

6. Research team

Please provide the names of all team members, their specialisation and the institution they represent in the project, especially if more than one institution is involved as a partner.

Enter text.