

**MUNI**

# **Masaryk university**

## **Research Ethics**

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*MU Legal Office*

# Ethical assessment of a project at MUNI

**WHICH** project needs an ethical assessment?

**WHY** is an ethical assessment required?

**WHOM** to submit my project for ethics assessment?

**WHEN** to submit my project to an REC?

**WHO** is supposed to submit my project?

**WHAT** part of my project is evaluated?

**HOW** to get an ethical approval of MU REC?

# WHICH project needs an ethical assessment?

Any research project involving

- human participants (biomedical, social/human science research)
- human biological samples (DNA, cells, tissues, liquids,...)
  - non-commercially available (from cooperating healthcare provider)
  - commercially available

Research project includes

- grant project (H2020, AZV, GAČR,...)
- internal faculty research project, GAMU
- dissertation

# WHY is an ethical assessment required?

An ethical assessment is important to ensure the protection of research participants.

Therefore an ethical approval is required:

- **by law** for biomedical research  
(see Oviedo Convention on Human Rights and Biomedicine)
- **by grant provider, science foundation**  
(see tender documentation)
- **by major scientific journals**  
(see editorial policy, always in biomedicine, often in psychology, research with vulnerable groups – children, patients)

# WHOM to submit project for ethics assessment?

## **MU Research Ethics Committee** (*Etická komise pro výzkum MU*)

- for all faculties (except Fac. of Medicine), CEITEC
- chair: *prof. Renata Veselská*
- secretary: *Blanka Jančková*
- submission by ISEP [https://inet.muni.cz/app/proj/navrh\\_find](https://inet.muni.cz/app/proj/navrh_find)
- Web site <https://www.muni.cz/o-univerzite/fakulty-a-pracoviste/rady-a-komise/eticka-komise-pro-vyzkum/o-komisi>

## **Ethics Committee Faculty of Medicine** (*Etická komise Lékařské fakulty MU*)

- chair: *Assoc. Prof. Josef Kuře*
- submission by email ([jkure@med.muni.cz](mailto:jkure@med.muni.cz))

**X Masaryk University Ethics Board** (*Etická komise MU*) – rector's advisory board in research misconduct (see Masaryk University academic and professional employee code of ethics)

# WHEN to submit my project to REC?

The project proposal has to be submitted **before the beginning of the whole project**, not only before the research data collection.

review ethical assessment – for changes in an approved project (design changes, new questionnaire added)

## submission deadlines:

- deadlines set for grant competitions (GAČR, AZV,...) – *ask R&D office*
- other submissions accepted:
  - MU REC: continuously (ASAP), min. 4 weeks before the expected beginning
  - Faculty of Medicine REC: 5th day of the month

# WHO is supposed to submit the project?

According to the internal MUNI directive, it is  
**the main researcher/proposer from MUNI**

...the person that should be mentioned in the ethical approval

# WHAT part of the project is evaluated?

- **project proposal** (detailed project description, not only an annotation!) including:
  - methodology
  - design of experiment
  - participants and their recruitment
  - description of the research team
  - personal data protection measures
  - questionnaire (in questionnaire survey)
- **inform consent** including:
  - explanation for participants
  - consent to personal data processing
- **letter of commitment** (participating organization, e.g. healthcare provider)

For templates see

<https://www.muni.cz/o-univerzite/fakulty-a-pracoviste/rady-a-komise/eticka-komise-pro-vyzkum/dokumenty>



# HOW to get an ethical approval of MU REC?

- create your project proposal in the ISEP (title, name, funding, duration, cooperation)
- apply for REC evaluation „Ethics=YES“

The screenshot shows the 'Project proposal editor' interface. The 'Ethics' section contains the text: 'Does your project need an assessment?' with radio buttons for 'yes' (selected and circled in red) and 'no'. Below this is a note: 'Every project that involves research is filed on behalf of any MU workplace. Ethics Committee is required by law retroactively, i.e. during or after implementation.' A dropdown menu for 'Investor 1' is open, showing 'Masaryk University' as the selected option. Other options include 'MU Development Fund', 'Grant Agency of the Masaryk University', and 'Internal projects of the CEITEC'. The 'Applied research' section has 'Among expected project results, is...' with 'yes' and 'no' radio buttons. The 'Project type' and 'Topic' fields are empty.

# HOW to get an ethical approval of MU REC?

The screenshot displays the 'Project proposal editor' interface on the inet.muni.cz website. The page is titled 'Project proposal editor' and shows details for proposal 0549/2017 (ID=59387), titled 'Testovací návrh - Etická komise pro výzkum MU'. The proposer is Mgr. Blanka Jančková, Ph.D., and the implementation period is 04.09.2017 - 31.12.2017. The status is 'working version', last changed on 31.05.2017 at 16:46 by B. Jančková.

The interface includes a navigation menu on the left with 'Research' and 'Links' sections. The main content area has a tabbed interface with 'Basic data', 'Ethics', 'Budget', 'Beneficiaries/Partners', 'People', 'Documents', 'Approval', and 'Authorization'. The 'Ethics' tab is highlighted with a red circle.

The 'Basic data' tab shows the following information:

Proposal reg. code	0549/2017
Project title	Testovací návrh - Etická komise pro výzkum MU
Acronym	
Proposer	Mgr. Blanka Jančková, Ph.D.
Implementation period	04.09.2017 - 31.12.2017
Investor's deadline	31.08.2017
Paper documentation location	Sekretariát EKV
Investor's reg. code	
Project categories	National/Foreign: <b>National</b> Grant/Non-Grant: <b>Non-Grant</b> Competence: Responsible MU unit: NES - Not specified Responsible academic officer: Unstated Final approving body: head of the economic unit Project support: Unstated
Investor 1	Masaryk University Program framework / project type: Internal projects of the Faculty of Science
Applied research	No
Ethics	Yes
MU role in project	Leading partner
MU economic / organizational unit	990000 - Rector's Office Subunit of MU Economic / organizational unit: 991700 - Research & Development Office
Other MU economic / organizational unit	
Pre-financing	Pre-financing is not allowed for the Investor 1 selected.
Brief Project Annotation	TestTestTestTestTestTestTestTest
Valid proposal	Yes
Note	

# HOW to get an ethical approval of MU REC?

- fill in basic information
- upload project documents for ethics (project proposal, informed consent, letter of commitment,...)

Information about the review procedure and instructions to the related documents find [here](#)

## A) Basic Information

Title of Project Proposal in English

Contact person (e-mail, phone)

Specify the panel, if the investor is the Czech Science Foundation (GACR) or the Czech Health Research Council (AZV)

Did the committee evaluate identical or similar project proposal in the past?  yes  no

Others informations

Related documentation - please upload project proposal, informed consent and other relevant documents (templates and instructions [here](#))

[+ Add document](#)

Record Management System file number: [528816](#)

Type	Subject	File	Barcode	Reference number	Changed	
návrh projektu		<a href="#">Penguins.jpg</a> 759,60 kB			31.05.2017 10:53 Z. Machač	

# HOW to get an ethical approval of MU REC?

- fill in the ethics questionnaire in ISEP/Ethics (to identify ethical topics in the project)

**B) Questionnaire**

**1. HUMAN EMBRYOS / FOETUSES**

1.1. Does your research involve Human Embryonic Stem Cells (hESCs)?  yes  no 🌐

1.2. Does your research involve the use of human embryos?  yes  no 🌐

1.3. Does your research involve the use of human foetal tissues / cells?  yes  no 🌐

**2. HUMAN SUBJECTS**

2.1. Does your research involve human participants?  yes  no 🌐

2.1.1. Are they volunteers for social or human sciences research?  yes  no 🌐

2.1.2. Are they persons unable to give informed consent or are they abilities to give informed consent somehow limited?  yes  no 🌐

2.1.3. Are they vulnerable individuals or groups?  yes  no 🌐

2.1.4. Are they children / minors?  yes  no 🌐

2.1.5. Are they patients?  yes  no 🌐

2.1.6. Are they healthy volunteers for medical research?  yes  no 🌐

2.2. Does your research involve any physical intervention on the study participants (including measurement of physiological parameters)?  yes  no 🌐

2.2.1. Does this intervention involve invasive techniques?  yes  no 🌐

2.2.2. Does it involve collection of biological samples?  yes  no 🌐

**3. HUMAN CELLS, TISSUES AND OTHER BIOLOGICAL MATERIAL**

3.1. Does your research involve human cells, tissues (other than from human embryos/foetuses) or other biological material of human origin?  yes  no 🌐

3.2. Does your research involve any type of genetic testing using this material?  yes  no 🌐

**4. PERSONAL DATA**

4.1. Does your research involve personal data collection and/or processing?  yes  no 🌐

4.1.1. Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?  yes  no 🌐

4.1.2. Does it involve tracking or observation of research participants?  yes  no 🌐

8.1. Does your research have the potential for military applications?  yes  no 🌐

**9. MISUSE**

9.1. Does your research have the potential for malevolent/criminal/terrorist abuse?  yes  no 🌐

**10. OTHER RELEVANT ETHICS ISSUES**

10.1. Are there any other relevant ethics issues that should be taken into consideration?  yes  no 🌐

# HOW to get an ethical approval of MU REC?

- submit the application to Research Ethics Committee MU

ERUX

Project proposal editor

Proposal 0549/2017 (ID=59387)  
Testovací návrh - Etická komise pro výzkum MU  
Proposer Mgr. Blanka Jančková, Ph.D.  
Implementation period 04.09.2017 - 31.12.2017  
Status of proposal working version  
Changed: 31.05.2017 16:46 Mgr. Blanka Jančková

Basic data Ethics Budgets Beneficiaries/Partners People Documents Approval Authorization

Changed: 15.03.2018 14:12 Mgr. D. Hozbová

Research Ethics Committee MU

Status Accepted for evaluation  
EKV No. EKV-2017-000  
Reviewer Members  
Mgr. MUDr. Petr Kachlík, Ph.D.  
Lawyers  
Mgr. Veronika Smitková  
Others  
prof. MUDr. Jan Novotný, CSc.

Information about the review procedure and instructions to the related documents find [here](#)

Finalize and submit to Research Ethics Committee MU

A) Project Information

Title of Project Proposal in English  
Contact person (e-mail, phone) 123456789  
Specify the panel, if the investor is the Czech Science Foundation (GACR) or the Czech Health Research Council (AZV)  
Did the committee evaluate identical or similar project proposal in the past? no  
Others informations  
Related documentation - please upload project proposal, informed consent and other relevant documents (templates and instructions [here](#))

Record Management System file number: 228816					
Type	Subject	File	Barcode	Reference number	Changed
návrh projektu		Penguins.jpg	759,60 kB		31.05.2017 10:53 Mgr. Z. Machač

B) Questionnaire

1. HUMAN EMBRYOS / FOETUSES

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1.2. Does your research involve the use of human embryos? no  
1.3. Does your research involve the use of human foetal tissues / cells? no

2. HUMAN SUBJECTS

10. OTHER RELEVANT ETHICS ISSUES

10.1. Are there any other relevant ethics issues that should be taken into consideration? no

Finalize and submit to Research Ethics Committee MU

# HOW to get an ethical approval of MU REC?

...what happens next...

1. 2 REC members and 1 lawyer review your proposal
2. in case of comments - discussion and completion of documentation
3. whole REC voting (most often per rollam)
4. REC secretary sends you (or not) an ethical approval of your project
5. Let's start your research!

*The role of RECs is  
to protect participants through research,  
not from research 😊*

## Contact:

Mgr. Veronika Smítková

*Legal Office*

*MU Rector's Office*

[smitkova@rect.muni.cz](mailto:smitkova@rect.muni.cz)