Consolidated text including changes in the Regulation No. 61 of the UL Rector of 12 December 2020;
Regulation No. 151 of the UL Rector of 17 May 2021;
Regulation No. 49 of the UL Rector of 5 January 2022

Annex to the Regulation No. 146 of the Rector of the University of Lodz of 3 July 2020

Rules of Procedure of the University of Lodz Research Ethics Committee

Chapter I
Legal basis for the establishment and operation of the Research Ethics Committee

§ 1

1. The Research Ethics Committee, hereinafter referred to as the "Committee", is appointed by the regulation of the Rector of the University of Lodz.
2. The committee operates during the term of office of the University of Lodz authorities.
3. The members of the Committee are determined by the regulation of the Rector of the University of Lodz.
4. The committee consists of at least 9 members.
5. Vice-Rector for research at the University of Lodz is the Chairperson of the Committee.
6. The Chairperson may appoint a member of the Committee to perform their tasks upon previous consent.

§ 2

1. Becoming a member of the Committee is voluntary.
2. Members of the Committee shall perform their duties until the first meeting of the newly appointed Committee or until further notice.
3. The Rector of the University of Lodz dismisses a member of the Committee in the event of:
   1) their resignation from membership in the Committee;
   2) termination or expiry of their employment relationship with the University of Lodz;
   3) withdrawal of the third party's recommendation granted to a member of the Committee who is a representative of this party;
   4) a court lawful decision for an intentional crime or a final conviction by the decision of the Disciplinary Committee of the University of Lodz;
   5) at the request of the Chairperson of the Committee, justified by serious reasons, in particular, the lack of participation in the Committee's activity or the disclosure of the information referred to in § 4 (2);
   6) refusal to submit the declaration referred to in § 4 (2).

Chapter II
Rules for application assessment by the Committee

§ 3

1. The object of the Committee's activity is processing applications for the approval of biological, medical, chemical and physical research projects using biological material collected from humans, as well as research interfering with human psychology, hereinafter referred to as "research".
2. The Committee acts in particular on the basis of competitions' guidelines announced by the National Science Centre in Krakow, the National Centre for Research and Development and other agencies granting funds for conducting research regarding the need to provide assessment on research experiments.
3. While issuing an opinion on the application, the Committee assesses the research provided for in the application in terms of compliance with the research ethics rules and protection of the research participants rights. The Committee may also take a position on the appropriateness of conducting the research provided for in the application as well as their scientific feasibility.
4. In matters not regulated by law, the Committee follows the adopted ethical standards.
5. The competence of the Committee does not cover matters which, by virtue of law, fall within the competence of other bodies.

§ 4

1. The Committee performs its tasks in accordance with the transparency and openness principles.
2. Members of the Committee and administrative employees participating in the Committee's meetings or preparing documentation for the needs of the Committee are obliged not to reveal confidential information obtained in connection with their work in the Committee and sign a letter of confidentiality, as shown in Annex 1 to this document.
3. The declaration, referred to in section 2, shall be submitted by a new member of the Committee within 14 days from the date of their appointment to the Committee, before the first meeting in which they will be participating.
4. Administrative employees shall submit the declaration, referred to in section 2, immediately after being assigned to work in the Committee.

§ 5

The Committee verifies in particular:

1) whether the research documentation and data collection forms are prepared in accordance with the requirements and principles of scientific integrity, without exposing research participants to the risk of injury, health damage or deterioration of health;

2) whether the qualifications of a researcher or researchers are sufficient for the proper conduct of research, applies also to auxiliary staff, in particular to people collecting biological material or collecting survey data;
3) whether the study groups and control groups were properly selected;
4) whether the proper supervision over the implementation of the research is ensured;
5) whether the information for the participant is comprehensible and contains all the required elements;
6) whether the requirements for the processing of personal data of research participants have been ensured;
7) whether there is any remuneration for the participants of the research and whether its amount may affect the voluntary participation in the study.

Chapter III
Requirements for conducting research

§ 6

1. The aim of the study must be to expand knowledge in a given field.
2. The research may be conducted with the use of materials from healthy and sick people. Such persons may also participate in psychological research.

§ 7

1. The study must not be conducted when participation may pose a risk of bodily harm or damage to health for healthy participants, or deterioration of health for sick participants.
2. Research involving a minor is not allowed if there is a possibility to conduct research of comparable scientific effectiveness with the participation of a person with full capacity to perform legal acts. Conducting research with the participation of a minor requires special justification.

§ 8

1. The voluntary consent of the person to participate in the study is required. The consent form may be found in Annex 2 to these Rules. It does not apply when the research is conducted using anonymous data (in particular, obtained from institutions such as the Central Statistical Office).
2. If the research is invasive or carries an increased risk for the minor, the consent of both parents is required. If the parents cannot reach an agreement, the matter is decided by the competent guardianship court. Such court decision shall be attached to the application referred to in § 12 (2).
3. In the case of a test that is invasive or involves an increased risk for the goods of the person who is to take part in the study, under legal guardianship, in addition to the legal guardian’s consent, a court authorization is required under the terms of art. 156 of the Family and Guardianship Code. Such court decision shall be attached to the application referred to in § 12 (2).

4. In the case of a medical experiment, including research of biological material, in particular, genetic material collected from a person for scientific purposes, the consents of the minor, who is over 13, and their statutory representative is required. If their positions are not the same, the applicant or the legal representative may apply for the case to be resolved by the competent guardianship court. Such court decision shall be attached to the application referred to in § 12 (2).
5. If the statutory representative refuses to consent to a minor under 13 to participate in a therapeutic experiment, the consent to conduct a therapeutic experiment may be granted by the guardianship court. Such court decision shall be attached to the application referred to in § 12 (2).
6. If the statutory representative refuses to consent to participation in a study different than a therapeutic experiment, conducting the study is prohibited.
7. The processing of personal data of a minor is possible only after obtaining the consent of their legal representative.

§ 9

Before giving consent, the research participant or his legal representative must be informed in an comprehensible and accessible way about:

1) the purpose of the research;
2) the method and conditions of the research;
3) expected scientific benefits;
4) the risk of participating in the research;
5) the possibility of withdrawing from participation in the research at any stage without bearing any negative legal consequences of such decision.

§ 10

1. The research participant or their statutory representative may withdraw the consent at any time.
2. The research should be discontinued if there is an unforeseen threat to the participant ‘s property during the course of the research.

§ 11

Information obtained in connection with the conducted research may be used only for scientific purposes. This information may be used in a way that prevents the identification of research participants.

Chapter IV
Organization of the Committee's activities

§ 12

1. The administrative management of the Committee is led by the Science Centre of the University of Lodz.
2. The Committee’s proceedings are initiated upon request of the person seeking an assessment, hereinafter referred to as the "applicant".
3. The application shall be submitted according to the template as shown in Annex 3 to these Rules. The template is available on the Committee’s website.
4. The application should be submitted within the time limit set by the Chairperson of the Committee specified by the Science Centre of the University of Lodz in the Announcement sent to the dean's offices and posted on the Committee's website.
5. The application shall be submitted together with the documentation presenting the research schedule, its purpose and planned benefits, as well as other required documents, in particular, the participant's consent form to participate in the study and the template of the information referred to in § 9.
6. The Committee considers applications submitted at least 7 days before the date of the Committee meeting.
7. The applicant submits the application to the Science Centre of the University of Lodz, whose employee checks whether the application and the documentation attached to it are complete and properly prepared in terms of formal requirements. If any errors are found, the application and documentation are returned to the applicant in order to change it or provide additional information. Failure to correct the errors within the prescribed period results in rejection of the application.
8. In the cases, referred to in § 3 (5), the Committee adopts a resolution to return the application due to the lack of competence to examine it. The resolution referred to in the first sentence may be passed, at the rapporteur's request, by circulation.

§ 13

1. The meetings of the Committee are convened by its Chairperson at least twice a year.
2. Members of the Committee are notified about a meeting by electronic means at least one week before its date. The notification specifies the list of topics and conclusions that are discussed during a given meeting.
3. Members of the Committee have the right to familiarize themselves with the documentation of the application that will be considered at a given meeting.

§ 14

1. The conclusions are presented at the meeting by the Chairperson of the Committee.
2. The Chairperson may invite the applicant and an expert in research discipline and methodology related to the assessed application to the meeting of the Committee.
3. Opinions are issued by the Committee in the form of resolutions.

4. The resolutions of the Committee are adopted in an open vote by a simple majority of votes in the presence of at least half of the members. The Chairperson of the Committee shall order a secret ballot at the request of a member of the Committee.
5. During the vote, votes are cast only "for" or "against" the adoption of the Committee's opinion. A member of the Committee, who is an applicant or who is in a service relationship with them does not take part in the vote.
6. The resolution of the Committee is signed by the Chairperson of the Committee.
7. The course of the Committee meeting is recorded. The written record is prepared by the Committee's Secretary.
8. The resolution of the Committee shall be delivered to the applicant in writing without undue delay but not later than within one month from the date of its adoption.

§ 15

1. In the event that the submitted application requires supplementing or correcting the errors, the Committee may issue a conditional opinion.
2. In the conditional opinion, the Committee specifies to what extent the application needs to be supplemented, what are the errors and how should they be revised. Following a conditional opinion, these guidelines are delivered to the applicant by the Committee's Secretary.
3. The applicant is obliged to submit a revised application within 14 days of receiving the information about the conditional opinion. In exceptional cases, justified, in particular, by the scope of additions or errors, the Committee may set a longer period, however, not exceeding 2 months.
4. The Chairperson of the Committee shall appoint a member of the Committee or a competent team with regard to the subject of the application and the type of errors to verify whether the application, referred to in section 1, has been corrected in accordance with the guidelines contained in the conditional opinion.
5. During the meeting of the Committee, the persons, referred to in section 4, submit a recommendation regarding the issuing of a final opinion on the application for which the conditional opinion was issued.
6. In the event that the errors are minor, the decision to accept the amended application is made by the Chairperson of the Committee.
7. In the event of an ineffective expiry of the period referred to in section 3, or failure to correct the application in accordance with the guidelines contained in the conditional opinion, the Committee shall adopt a resolution containing the negative opinion.

§ 16

1. The applicant may appeal against the negative opinion to the Rector of the University of Lodz through the Committee within 14 days from the delivery of the opinion.
2. The Rector of the University of Lodz may uphold the appealed resolution or refer the matter for reconsideration at the next meeting of the Committee, specifying the guidelines the Committee must follow while reconsidering the application. Upholding the resolution by the Rector of the University of Lodz is final.

3. The committee examines the resolution submitted by the Rector of the University of Lodz for reconsideration at the next meeting. In exceptional cases, it is possible to convene an additional meeting to consider the appeal. The Chairperson of the Committee may appoint a team of at least three members of the Committee to present their position on the appeal.
4. The Committee may consider the appeal against the previously adopted resolution, submitted by the Rector of the University of Lodz for re-examination, as justified, and amend the resolution in the direction expected by the applicant. If the Committee does not consider the appeal to be justified, it shall send it along with the application documentation within 7 days from considering the appeal by the Rector of the University of Lodz.
5. The provision of section 2–4 shall not apply to applications rejected in the appeal procedure.

§ 17

1. Resolutions of the Committee and applications with their documentation are archived in the Science Centre of the University of Lodz for a period of 3 years from the end of the case, and then transferred to the University of Lodz archives.
2. The University of Lodz Science Centre may issue copies of the Committee's resolutions to the applicants and other authorized persons.

Annex 1 to the Rules of Procedure of the Research Ethics Committee of the University of Lodz

Sample declaration for a member of the Scientific Research Ethics Committee of the University of Lodz

Lodz, on _____

_____

name and surname

_____

address

_____

PESEL (personal identification number)

Declaration

I declare that I undertake not to disclose and not to use the information received in the course of work at the University of Lodz Research Ethics Committee.

At the same time, I declare that I know that in the event of disclosure of confidential information, I may bear criminal and civil liability before the competent common court.

_____

legible signature

Annex 2 to the Rules of Procedure of the University of Lodz Research Ethics Committee

***CAUTION !!!!** Red colour marks the fragments which, depending on the situation, will or will not be included in the content (the text and its colour should be unified before filling in and printing).*

The consents do not need to be collected if the research is conducted with the use of anonymous data.

Data that should be included in the consent form to participate in research:

.....
title of the study

.....
name and surname of the person conducting research

....
description of the study

Research participant data:

name: ……

surname: ……

With my signature, I certify that:

1. My participation in the study is voluntary and I was able to refuse to participate without any negative consequences for the refusal.
2. The purpose of the study was introduced and explained to me.
3. I was informed about the method and conditions of the research.
4. I was informed of the expected scientific benefits.
5. I am aware of the risks of participating in the study.
6. I am aware that I can withdraw from the research experiment at any time without bearing any negative legal consequences of such a decision.
7. I am aware that the documents related to me will be confidential and that the information obtained in connection with the conducted experiment will be used only for scientific purposes.

☐ I consent to the processing of my personal data by the University of Lodz within the scope of

.....

(please enter the scope of data, e.g. name and surname, voice, blood samples, etc.)

and for the purpose necessary to conduct the study ……

……

(please indicate the title of the study, the person conducting the study and the organizational unit they represent)

☐ I consent to the processing of data for the purpose of contacting me regarding further research.

☐ I consent to the processing of data for the purpose of …… ..[1]

I am aware that my consent may be revoked at any time, which will result in the removal of my data.

I have read the information on data processing below.

name:……

surname:……

legible signature:……

place and date: ……

Data of the representative / legal representatives, expressing / giving consent, if required:

first name:…… ……

surname:…… ……

legible signature: ……

place and date: ……

Personal data processing for research participants

1. The administrator of your personal data is the University of Lodz, Narutowicza 68, 90-136 Lodz.
2. Contact to the Data Protection Officer of the University of Lodz at the above-mentioned address with a note: Data Protection Inspector of the University of Lodz or via e-mail to the following e-mail address: iod@uni.lodz.pl
3. Personal data will be used to conduct a study entitled ……
   ……[2];
   (please provide the title / name of the study)
4. Personal data will be processed on the basis of your consent.
5. The obtained data will be processed and stored for the time necessary to achieve the purpose referred to in point 3, and then for the period of ..... *(e.g. evaluation, reporting to the financing entity)* or until the consent is withdrawn. After the research is completed, the data will be anonymized or pseudonymised.
6. The data will be made available to authorized employees of …… *(name of the research unit)*, they may also be made available to authorized entities on the basis of relevant provisions and agreements concluded with the University.

[1] A separate consent must be obtained for each separate processing purpose.

[2] If personal data is collected for several purposes, e.g. to contact the research participant again, it is indicated in this point (all processing purposes are listed here).

7. *Personal data will / may be transferred to a third country or international organizations. A third country is a country that does not belong to the European Economic Area*[3].
8. You have the right to:
    1) access the content of your data;
    2) correct the data if it is inconsistent with the actual state;
    3) delete the data, limit processing, as well as transfer data - in cases provided for by law;
    4) object to data processing;
    5) withdraw from the consent at any time without affecting the lawfulness of the processing which was carried out on the basis of consent before its withdrawal;
    6) submit a complaint with the supervisory body, which is the President of the Personal Data Protection Office with its registered office in Warsaw, Stawki 2.
9. Providing your data is voluntary but necessary for the research to be conducted.
10. *Your data will be processed in an automated manner and will be profiled*[4].

The processing of personal data is carried out on the basis of art. 6 sec. 1 lit. a) and art. 9 sec. 2 lit. and)[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46 / EC (general regulation on the protection of personal data ; Polish Journal of Laws (General Data Protection Regulation; Official Journal of the European Union L.2016.119.1) – "GDPR".

[3] If personal data will not be transferred, among others to third countries / international organizations, this point should be deleted. If they are transferred, please consult the content of this clause with the DPO before starting the research.

[4] If personal data will not be processed in an automated manner and will not be profiled, please delete this point should be deleted.

[5] Applicable herein if the data of a specific category is processed.

Annex 3 to the Rules of Procedure of the Research Ethics Committee

University of Lodz

Applicant's data:

…….
name and surname (degree or academic title)

…….
name of the organizational unit of the University of Lodz / external entity

…….
contact details: telephone number or e-mail address

Application number ..... / .... *(to be filled in by the secretary of the University of Lodz Research Ethics Committee)*

Date of application .....

APPLICATION TO THE UNIVERISTY OF LODZ RESEARCH ETHICS COMMITTEE ON GIVING OPINIONS ON CONDUCTING RESEARCH

I. **Nature of the research** *(e.g. as part of a research project; statutory activity; doctoral thesis, master's thesis, etc.)*:

……
……

II. **Research supervisor** *(name and surname, title and academic degree, specialization)*:

……
……

III. **Research topic:**

……
……

IV. **Place of research:**

……
……

V. **Research period:**

……
……

VI. Aim of the research:

……
……

VII. Description of the used procedures *(e.g. preparation of the questionnaire, recording conversations, writing down immediately after the conversations, taking samples of biological material)*:

……
……

VIII. Defining study groups:

1) **Category of research participants** *(e.g. patients, students, white collar workers, clients; if not identifiable, please indicate)*:

……
……

2) **type of personal data collected in connection with the conduct of research:**
   a) **personal data** *(e.g. name and surname, PESEL (personal identification number), address, correspondence address, e-mail address, telephone number, IP number, education, age; if not collected, write - not applicable)*:

……
……
……

   b) **special category data** *(data related to health, e.g. sobriety, bulimia, drugs - addictions, cancer, mental diseases, stigma, trauma; data concerning disability; issues related to religious affiliation, sexual and ethnic minorities; biological material; if not collected, write - not applicable)*:

……
……
……

If biological material is used in the research, points XI and XII of this application should also be completed.

3) **Data source:**
   a) data obtained directly from the respondents
   ……
   ……
   b) data obtained indirectly, *e.g. from other public institutions (hospitals, NFZ, GUS, etc.) or private entities*
   ……
   ……

4) **What type of data is obtained in connection with the research:**
   a) only data on respondents *(YES / NO)*;
   ……
   ……

b) data on people in relationships with the respondent *(e.g. relatives: children, parents, siblings, spouses) - if so, please indicate these categories of people, if not, write - not applicable*

……
……

IX. Place and method of collecting the material and the person's right to download it:

……
……..……..

X. The method of handling data obtained for the purposes of the research *(e.g. with personal data)*:

1) legal basis for the personal data processing *(e.g. consent to the personal data processing for the purpose of conducting the research)*:

……..……

2) purpose / purposes of personal data processing

……..……

3) data minimisation *(only data necessary to achieve the purpose of the study are collected)*

……
……

4) data storage period *(please specify how long the data will be stored, e.g. for the duration of the study; and when they will be destroyed / removed)*:

……
……..……..……..…….

5) data security (equipment on which it is processed, encrypted, etc.) *(e.g. data is only stored on properly secured university equipment)*:

……
……
……..……..……

6) data deletion, data anonymisation or pseudonymisation:

……
……..…..

7) rules of sharing (if the data is not anonymised)

……
……

XI. Usage of biological material obtained for the study (if applicable):

1) biological material storage period

……

2) rules of utilization of the biological material

……..

3) use for further research (if applicable)

…….

XII. Rules for handling the collected biological material and other data in the event of liquidation of the storage unit or termination of the study director's employment relationship:

……

……

The following documents have been attached to the application, completed electronically or in writing:

1) template of the consent form for participating in the study; **
2) data processing consent form (along with the information clause); **
3) other ……..

I declare that the information, including personal data (also in the form of samples of biological material), will be used only for scientific research.

I undertake to maintain the confidentiality of personal data of the research participants and to comply with the provisions of law.

……
legible signature of the Applicant

……
*legible signature of the academic supervisor***

……
place and date

*** If applicable.*