Instructions for preparing applications for assessment of the ethics of research

Ethics assessment

The purpose of an ethics assessment is to determine, based on a comprehensive review of the key elements of the research, whether the proposed research adheres to the existing ethical rules and standards and its implementation can therefore be approved. The role of the researcher requesting an ethics assessment is to clearly describe and present all those elements of the planned research that are important for ethical assessment. In order to ensure effective ethics assessments, the University of Ljubljana Human Research Ethics Committee (KERL UL) has defined standard elements and the design of the application for ethics assessment.

It should be noted that an application for assessment of the ethical suitability of research constitutes the researcher's commitment as to what kind of research will be conducted and how. Any deviation from the confirmed application automatically annuls the approval of the Human Research Ethics Committee. If for any reason elements presented in the application need to be changed, prior to implementation of the research the approval of KERL UL must be obtained for the planned changes.

Structure and design of application

Applications for ethics assessment must be created and submitted in the form of an electronic document in A4 format and in standard 10 pt font. The application must first set out briefly the basic information on the planned research project, then present the following content sets:

1. Basic data on the application
2. Introduction
3. Participants
4. Research plan
5. Procedure
6. Consent to participation
7. Protection and confidentiality of data
8. Assessment of possible risks and benefits of participation
9. Annexes

The individual sets are described in detail below.

1/ Basic data on the application

The first part of the application should provide on one page key information on the proposed research assignment. The following information should be highlighted:

- the full and abbreviated title of the research assignment;
- who is the priciple investigator or mentor, who the other researchers are, and who are the persons collecting the data;
- the research field;
- the proposed type of ethical treatment with substantiation;
- type of study.

In the second point the applicant adheres to the following definitions:

- applicant – the person who submitted the application for assessment of the ethical suitability of the research and who has the approval of the primary investigator and research group to represent it in communication with KERL UL;
- principle investigator – the person who heads the proposed research and is responsible for its appropriate plan, preparation and implementation;
- researcher – a person who collaborates in and substantively contributes to the formulation of the research in an individual or every stage;
- investigator – the person who under instruction from the principle investigator or other researchers carries out specific tasks for the needs of implementing an individual stage or several stages of the research;
- project group – a group of researchers that includes the principle investigator and other researchers participating in the preparation, planning and implementation of the proposed research.

In the penultimate point the applicant's task is to specify whether this involves research that does not require any ethics assessment, research with minimal risk or research that exceeds minimal risk. Here the specification must be adequately substantiated through a review of key criteria (described in detail in the document *Criteria of Ethics Assessment*).

In the final point the applicant specifies what kind of study is involved and how it is financed. Does it involve independent research, is it part of a broader financed research project, is it a doctoral or master's project and so forth.

Before submitting the application the applicant has the job of checking whether it contains all the fundamental elements necessary for an assessment, for which the applicant uses a checklist to be submitted as an appendix in a separate document.

2/ Introduction

The purpose of the introduction is to briefly describe the key principles of the research. It should set out the fundamental existing literature and research findings in the field of study, substantiate the need in respect of the proposed research, describe the key hypotheses and aims of the research and summarise the expected significance and contribution of the planned research. The introduction must make it clear that the research is mapped out logically and will facilitate the gaining of knowledge and findings that will more than outweigh the anticipated investment of energy and effort from participants. The introduction should be concise and should not exceed one page of text.

3/ Participants

Number and description of participants

The number of participants should be sufficiently large to enable verification of the presented hypotheses. Due to the possibility of participants dropping out and results lost for technical reasons, it is acceptable to plan for work with a somewhat larger number of participants than is necessary, but any excessive increase in the number of participants is not acceptable. Where possible it is desirable for the reasons given for the planned number of participants to be supported by appropriate analysis of the strength of the study. In the description of participants the planned sample of participants should be clearly defined and you should set out the inclusion and exclusion criteria on the basis of which participants will be selected. These need to ensure that neither in inclusion or exclusion from the possibility of participating in the research there is no kind of unjustified bias or discrimination. Where this involves probability sampling, the method and procedure for probability sampling should be described. Where it involves non-probability sampling, which does not allow for statistical conclusions regarding the observed population, the method and procedure of sampling should also be defined, with an explicit statement of the limitations in drawing conclusions for the population and the procedures of verifying conformity between the actual and planned sample. In qualitative sampling there should also be a definition of the method and procedure of sampling and a description of the methods of theoretical assurance of the sample quality.

Method used for participant recruitment

In this section the researcher must describe the method of formulating the sample and the means by which participants would be recruited to participate in the research. On the one hand it should be ensured that potentially interested individuals have equal prospects of participating in the research, and on the other hand there is a need to avoid any manner of coercion to participate in the research or of obtaining participants by fraudulent means. Participation in the research must always and in every case proceed from the individual's free choice and decision based on clearly presented key information about the research.

In assessing the voluntary nature of participation it should be taken into account that coercion can arise in very varied, sometimes nearly imperceptible forms. Participants must always know that their participation is entirely voluntary and that in no way at all does their wellbeing depend on it, either in a positive or negative sense. For any individual that declines participation in the research, there can be no negative consequences, explicit or implicit, actual or imagined. Special care should be taken to ensure that participants do not agree to participate in the research due to social pressure or the pressure of some authority. On the other hand an individual who decides to participate in the research may not expect any benefit that would go beyond the knowledge and experience gained through participation, a minimum compensation for time and effort invested and reimbursement of costs directly associated with participation. A large cash reward, the promise of a better grade or privileged treatment constitute inappropriate forms of inducing people to participate in the research.

The description of the planned method of obtaining participants must make it clear how participants will find out about the research, who will address them and what information about the research they will receive. Especially in situations where there could be a feeling of coercion, it should be explained in detail how participants will be assured that their participation is entirely voluntary.

In the case of standardised surveys, the invitation to participate in the survey (in person, telephone or online) must contain all the above-mentioned key information. In this case we may assume that the participant has read through (or heard, in a telephone survey) and understood the key information and agrees with what has been stated when they agree to participate in the survey. Examples of best practices in inviting people to participate are the letter and brochure inviting participation in the European Social Survey (http://www.europeansocialsurvey.org/docs/round7/fieldwork/slovenia/ESS7_letters_to_respondents_SI.pdf), conducted by the CJJMK http://www.europeansocialsurvey.org/docs/round7/fieldwork/slovenia/ESS7_brochure_SI.pdf.

Possible compensation for participation

By participating in the research study, participants offer the researcher their time, energy and goodwill, and often enough participation involves additional costs. Where possible, participants should be given appropriate compensation for their time and they should be reimbursed for any costs. In the application you need to clearly note what kind of compensation participants will receive, and for what. If the research does not envisage any funds for compensation, this also needs to be pointed out. Special care should be taken to ensure that the envisaged compensation does not exceed the actual costs and rational level of reimbursement for time spent. Payment and financial incentives for participation are not acceptable, for the reasons given in the preceding point.

4/ Research plan

Within the research plan the researcher presents the fundamental roadmap of the research. Here it should be noted which research plan will be used (e.g. survey, experiment, interview, focus group, triangulation) and which variables (dependent and independent) will be measured. Where the research is qualitative, it makes sense to define the key relevant concepts. In this part describe how many groups the participants will be divided into, how the groups will be differentiated from each other and what variables (factors and their levels) will be controlled and measured. In this part, you should also outline the planned time frame for the research, with information on the envisaged time for a) preparation, b) obtaining participants and collection of data and c) analysis of the data. In this part you should also note any possible information on collaborating organisations and their agreement to participate in the research study.

5/ Procedure

Within the procedure a detailed description should be given of the implementation part of the research assignment. The content of this chapter depends on the research field and the approach used in the research. The most common content is a description of instruments and tests used and instructions to participants.

List of instruments and aids

In this part the researcher states all the instruments and aids they intend to use in the research. Next to each instrument a brief description and its purpose are provided. Where this involves standard instruments and aids, add a relevant reference where the instrument is described. The same goes for the use of secondary data and sources (e.g. Archive of Social Science Data, GESIS, ESS). Where an instrument

is involved that has been developed by the researcher, a detailed description of its essential features and specifications should be given. In stating the instruments a note should also be made of who will use them, and information should be provided on their qualification to use them. An estimate should also be given of the duration of use of an individual instrument.

Description of experimental tasks and procedures

If the research includes the conducting of one or more behavioural tests or other experimental tasks or procedures, the researcher must give a detailed description of each of them in this part of the application. In the description, present the stimuli used and the conditions, the progress of the test, the participants' task and the variables measured. The researcher should also set out information on the number of attempts and possible breaks, and an estimate of the overall time needed to conduct the test.

Instructions for participants

In this section the researcher describes the instructions that will be given in each part of the research implementation. If the instructions are standardised, add this as an addendum to the application.

The description of the procedure should conclude with an overall estimate of the duration of the entire protocol of conducting the research.

6/ Consent to participation

Obtaining informed consent for participation in the research is one of the fundamentals of ensuring the ethically appropriate conducting of research. The participant's consent is generally confirmed with the signature of the form *Informed Consent for Participation in Research*. The content of the form is described in detail in the document *Informed consent: instructions for preparation*, and the prepared form attached as an annex constitutes a fundamental part of the application for ethics assessment. The task of the researcher in this section is to describe how consent will be obtained; in the case of consent obtained verbally, the reasons for omitting to obtain signed consent in writing must be additionally substantiated; in the case of research that includes deception, you should additionally present the procedure of debriefing after data collection is complete.

Obtaining consent

The task of the researcher is to describe when and how participants will be presented in detail with the research assignment and other elements that involve informed consent, and for participants to have the opportunity to pose any questions on the purpose of the research and details of their participation. Where possible it is important for the researcher to present the research, respond to questions and obtain consent through personal contact. Indirectly obtaining consent through the mail or through the intervention of teachers or school pupils is not appropriate, since this does not enable participants or their guardians to pose possible questions and to be fully informed about the research before giving consent. Where given the nature of the research the researcher cannot personally obtain consent, they may entrust the presentation of the research to their associates, who must be appropriately informed of all the key elements of the research. In this case the informed consent form should be signed by the associate who presented the research.

In the procedure for obtaining consent it is extremely important for the associate to be focused on the actual participant in the research. This also applies in the case of participants who are minors or participants who have been assigned a guardian. If such participant is able to read, they should also read through and sign the informed consent form, and the wording of the form must be appropriately adapted to their level of understanding. If the participant is not able to read, the researcher's task is to present to the participant verbally all the key points of the consent and to be sure they are understood. It is best to ensure understanding by having the participant repeat the essential points and present them in their own words. The participant's consent is received only when the participant in the research fully understands what the purpose of the research is, what is expected of them, what the benefits and risks are of participation, and also that their participation is entirely voluntary and can be terminated at any time without consequence. The parents or guardians should only confirm the consent, and this in cases envisaged by the relevant legislation (e.g. the Family Code, Convention on the Rights of Persons with Disabilities, the GDPR).

Omission of written consent

In some cases written consent is not desirable or can be almost impossible to obtain. One possible reason is research where just the knowledge that an individual participated in the research would represent an unacceptable level of risk for the participant. An example of such research is for instance a study of the sexual behaviour of persons infected with HIV. If it is possible to provide appropriate assurance of obtaining verbal consent, written consent for such research can be waived.

Another example is research in which the obtaining of consent would directly affect the research results and prevent the studying of the research question. Such cases include studies based on observation and/or controlling of a social situation where the prior obtaining of informed consent could fundamentally change the behaviour of the individuals and their group interaction. Similar is true of studies where the research plan is based on various forms of deception or it is required that the participant is not aware of certain stimuli or aspects of the research plan. Where such research involves nothing more than minimal risk for the participant, critical content may be left out of the informed consent or it may be entirely omitted.

In both stated cases the researcher's task is to set out in the application substantiated reasons for omitting informed consent, while also demonstrating that all the other necessary conditions have been met.

In certain cases (e.g. opinion polls, online surveys), agreement to participate is demonstrated by acceptance of the survey conductor and the start of the survey (assent to a telephone survey, receiving the survey conductor at home, completing an online survey). In such cases the invitation to participate must include all key information about the substance of the research, the researcher and the research institution, the procedure for selecting participants and the procedures for ensuring anonymity and confidentiality, which of course include informed consent. This information must be communicated to potential participants (in writing or verbally) before any data are collected. Data collection can only begin when the participant gives unequivocal agreement with the information provided, be it in the form of verbal assent (e.g. for a telephone survey) or in the form of clicking on a button before starting participation in an online survey. Examples of best practices in inviting people to participate are the invitation to participate and the explanation of the key information as formulated by the European Social Survey

(http://www.europeansocialsurvey.org/docs/round7/fieldwork/slovenia/ESS7_letters_to_respondents_SI.pdf).

Debriefing on the research

In the case of studies that omit consent or modify it due to the requirements of the research plan, after the research an appropriate debriefing needs to be held with the participants, where participants are shown the actual nature of the test and the reasons for omitting consent or for the deception, and consent is then obtained for using the data collected. The researcher's task is to present when and how the debriefing and obtaining of consent to use the results will be conducted. If the reporting on the research has been prepared in written form, the researcher should attach this to the application. Where prior to collecting the results no consent has been obtained, consent to the use of results after data has been collected must be obtained in writing. Where written consent has already been obtained, following the debriefing verbal consent should be obtained for using the results, or the participant should be enabled to withdraw from the research. The procedure must be in both cases appropriately presented in the application.

Withdrawal of consent

Participants may withdraw their consent to participate in the research during the collection of data and also at any time after the conclusion of the research. The researcher's task is to delete the data collected from the participant and withdraw it from the research, if this is actually and technically possible. In order to facilitate this possibility, the participant must be given contact details for contacting the primary investigator or implementing researcher.

If the participant expresses the wish to withdraw from the research during the process of data collection, the collection of their data should cease, and all data including identification and demographic data should be irredeemably destroyed, and the participant notified of the deletion and thanked for their participation.

If the participant expresses the wish to withdraw from the research after data collection is complete at a time when it is possible to still identify their data, all the participant's collected data should be irredeemably deleted, including their identification and demographic data.

If the collected data are already de-identified, the participant can supply information that enables the unambiguous identification of their data, and the participant's data is then irredeemably deleted, including any record of their participation in the study and demographic data.

If the collected data are already fully de-identified and it is not possible to identify them in a reasonable time through reasonable effort, the participant should be notified that their data cannot be identified among the data of other participants and therefore cannot be deleted. In this case only possible data on the identity of the participant are deleted, and other data remain in the database.

The application for ethics assessment must include information on until when and how the participant can withdraw consent to participate, and how and in what scope it will be possible to delete the participant's collected data.

7/ Protection and confidentiality of data

Protection of the participant's privacy is one of the fundamental tasks of the researcher. At all stages of the study the researcher must ensure the highest possible level of protection of collected data, and prevent the possibility of data being identified, i.e. linking collected data with a specific participant. Researchers can protect the security and confidentiality of data in the following ways.

Total anonymity. The best way of ensuring the security and confidentiality of data is to maintain total anonymity of collected data at all stages of the study. In this case the collected data contain no information that could identify a participant. Not even the researcher has information on which data pertain to a participant. This level of data protection is possible for instance in online surveys, which do not ask for any personal data.

Pseudonymisation of data. In the case of studies that require mutual linking of the results of various tests and methods of data collection, or data must be merged via several time points of data collection, the best solution is to formulate random research codes. In this case each participant is given a unique, completely randomly set research code under which all their results are stored. It is important that such research does not use codes from which it would potentially be possible to reconstruct whom the data pertain to. An example of this would be a code made up from abbreviations of the personal name, the mother's name and date of birth. Although such codes give the impression of randomness, the information on which they are based can easily be obtained and then it can be determined which results pertain to which participants. The code must be formulated in such a way that it is impossible to reconstruct from it who it pertains to, nor is it possible based on information about the participant to reconstruct the code they used or were assigned.

Another important requirement in using the pseudonymisation of data is that the document that stores the link between the identities of participants and the assigned research codes should always be kept physically separate from the collected data and appropriately protected. Appropriate protection may be storage of a printed document in an adequately secure safe or a digital version of the document on an appropriately password-protected disc, USB stick or file. Physical access and the password should only be provided to those persons who need the data for conducting measurements or for merging data after measurements are conducted.

Total anonymisation of data. As soon as data collection in the study is concluded and all the collected data are merged under a unique random password, it is rational and necessary to physically destroy or irredeemably delete all records that link the research passwords to the identities of participants. In this way the data become fully anonymised.

Delaying total anonymisation is only rational and permissible in appropriately justified cases, such as planning repeat measurements, in the event of envisaging a follow up study for which the mutual linking of data is important, or in a justified need for possible renewed contacting of participants to obtain additional information. In the temporary and also long-term extension of storing identification data, security of access to identifying data must be stringently imposed. Access may be allowed only to authorised persons, who cannot conduct the research without it. It is recommended (and in some cases legally required) to implement a system of recording access to identifying data.

Where due to the nature of the research or the nature of the data collected it is not possible to perform total anonymisation of data, it is recommended that data be stored at organisations that can facilitate

appropriate security for storage and access to data. Such an organisation is for instance the Archive of Social Science Data at the Faculty of Social Sciences (https://www.adp.fdv.uni-lj.si).

The researcher's task is to define in detail the methods of ensuring data protection in cases of exchanging and sharing data with other researchers or research groups collaborating in the research.

Identifiability of data

In managing data it should be remembered that certain data can be recognised and may be identified despite storage under completely anonymised passwords. One such case is where data relate to a very rare and clearly recognisable group of individuals. In research that covers the autobiographical data of all the presidents of the Republic of Slovenia, despite total anonymisation of research codes the data could be quickly identified. There is a similar case with anthropological studies, where individuals describe for instance the personal history of a family in a small village in the Karst. In these and related cases, due to the nature of the sample and the data collected, the data cannot be considered to be de-identified. In these cases the researcher has a few options. The first option is to obtain from participants written consent to be able to use the data and publish them despite the possibility of identification, or for the participant even to agree to full identification. Another option is for the researcher to leave out, conceal or appropriately replace all data that might identify a participant in published results. In cases where data can be identified as they are, the data must be stored securely and protected in the same way as completely identified data. Special care should be devoted to ensuring the non-identifiability of data in cases where the researcher intends to share raw data, be it in public repositories or with third persons.

Another case where additional care must be taken for privacy, is studies that contain biometric data based on which it is possible to identify individuals. This group includes for instance genetic data, physical details of an individual or high-resolution structural images of a head. In all these cases it is possible through relatively accessible technology to identify the individual to whom the data relate. In such situations it is important for data either to be modified so that identification is no longer possible, or to be treated as fully identified data and then given appropriate protection. In specific fields tools already exist for the de-identification of data. In the field of structural images (e.g. MR or CT) of the head, specific tools enable the removal of that part of the image that would enable facial recognition (defacing). In other fields other technologies and tools may exist.

Extra attention must be given to various metadata that can automatically be stored in the use of various data collection techniques. In files that store the results of structural or functional imaging of the brain or other parts of the body, data can be stored relating to the name of the participant or the precise time of data capture. In a similar way, data collected using online tools include the IP number of the participant's computer and the precise time of doing the online test or questionnaire. Such data must be recognised and either deleted or appropriately modified so that identification of the participant is no longer possible.

Within the section Protection and confidentiality of data it is the researcher's task to critically assess the nature of the collected data and the possibility of their identification, and to envisage and present adequate protocols for data protection. The researcher should describe whether the research will collect totally anonymised or pseudonymised data. In the latter case they should describe how passwords will be created, how the security of identification data will be ensured and when the data will be deleted. They should also describe the methods used to prevent identification of the participant from collected data. If full de-identification is not possible, they should present how safe storage will be provided, along with access to

collected data, and how the identity of participants will be protected in the publishing of results of the study or on the publishing of data in a publicly accessible repository.

8/ Assessment of possible risks and benefits of participation

Participation in research inevitably involves various risks and benefits. These may be direct (the participant is exposed to dangerous stimuli, the participant receives monetary compensation for participation) or indirect (owing to participation the participant may be stigmatised, the participant receives useful knowledge and information about themselves or the field of research or the possibility of priority treatment). In this section the researcher's task is to clearly set out and critically evaluate all the direct and indirect risks and benefits and how they are addressed.

In evaluating risks, the researcher is bound to describe how the risks will be presented to participants and what procedures and measures will be included in the research to reduce risks and address possible consequences. Cases of risks may be relatively minimal, for instance a feeling of boredom or fatigue, which can be dealt with through adequate breaks. But they may also be more serious, such as arousing negative experiences and feelings on the presentation of emotionally charged stimuli or in posing questions or holding conversations related to traumatic experiences of the participant or those close to them. In the application the researcher must weigh up critically what consequences there might be, and include in the research process protocols for identifying negative consequences and addressing them.

Where there is the possibility of arousing traumatic memories, during data collection and upon its conclusion there should also be appropriate checking of the psychological wellbeing of the participant. The researcher should envisage the possibility of psycho-social assistance, include an appropriate expert in the research and provide participants with information on how the expert can be contacted.

In the case of research that includes group communication (e.g. a focus group, group interview or intervention in groups), the risk of disclosure of the personal data of co-participants should be foreseen. The researcher must appropriately foresee such situations and describe how they will be addressed (e.g. commitment of attendees to the secrecy of meetings).

In some research, either by means of the instruments used or through conversation, a threat to the health or wellbeing of the participant or third persons may be revealed. For instance in using questionnaires on depression, it may be possible to identify a risk of suicidal behaviour, and the use of imaging techniques may lead to the random discovery of anatomic anomalies, tumours or other disorders. In all these and similar cases, there is a need to envisage how such situations will be recognised, and a protocol needs to be created for addressing exceptional cases where there is a clearly envisaged response procedure and further action in line with the protection of the participant's privacy and wellbeing.

The researcher must also critically evaluate the benefits of participation and assess whether in particular the direct benefits are proportionate to the invested effort and risk, or go beyond it significantly and can be considered a form of inappropriate inducement counter to the principle of voluntary participation. In a similar way it is necessary to avoid positive discrimination where the participant might be given priority treatment over other individuals who cannot or do not want to participate in the research.

9/ Annexes

The final part of the application should list and briefly describe all the annexes that comprise the full application for ethics assessment. The annexes should include at least the informed consent form. It is advisable to include in the annexes examples of advertising of the study, of reaching out to potential participants, written materials that participants receive, descriptions and/or examples of non-standard instruments, examples of stimuli used in the study, an example of the protocol or instructions for those conducting the study, the protocol for dealing with exceptional cases and the protocol for protection or total de-identification of data. Annexes are always welcome when they provide specific example of addressing elements of ethics assessment or when it makes no sense to include a detailed description of the procedure for the sake of transparency in the main text of the application.