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Guidelines

FOR ETHICAL CONDUCT IN RESEARCH INVOLVING PEOPLE

1. The need for ethical assessment

The care for the benefit of participants in research represents a fundamental ethical principle of scientific research. The primary concern of ensuring ethical conduct is the responsibility of persons designing and conducting research. They have to be familiar with the relevant laws (e.g. Personal Data Protection Act) and rules and codes of ethics of particular professions and scientific disciplines in which they work. The fundamental trust in ethical conduct of researchers notwithstanding, it should be noted that scientific research can be, in spite of the primary goal of progress of society, occasionally in conflict with the interests and well-being of individuals participating in research, and designers and performers of research can have conflicts of interest.

In order to ensure in every case optimal protection of interests and well-being of participants in scientific research, the process of its preparation must ensure protection of personal information and application of ethical assessment criteria.

2. Personal data protection

The Personal Data Protection Act has been primarily drafted for the maintenance of extensive permanent databases of personal information, which have a distinct requirement of identification of stored data. From the aspect of scientific research, it is important to distinguish between personal data and identified data. Research is often based on analyses of personal data with no need for identification. All data in research are therefore kept in de-identified form, i.e. in a manner making it impossible to determine to who the collected data refers. If possible, a complete de-identification of data will be performed upon collection (e.g. by submitting anonymous surveys), if not, the collected data and the list through which data can be linked to the identity of participants are always kept separate. The list will be destroyed to prevent data identification as soon as such link is no longer necessary. In the language of the Personal Data Protection Act, data is “unblocked”.

In practice, an identification list is always kept only by the primary investigator who will submit it if necessary to only those researchers who require access to it to perform their work. The number of persons who may identify data and the possibility of abuse are thus minimised.

Such manner of conduct makes personal data databases superfluous and the formation of on-line

databases and designation of their custodians represent an unnecessary complication and security risk. The described manner of data handling (data always stored in de-identified form) results in the UL (and its researchers) avoiding the need for complex procedures for personal data protection described in this document and the assuming of unnecessary responsibilities.

In practice, the aim is to collect only that data which is urgently needed to conduct research and the access to identification data is limited only to those individuals who need it and solely for the periods in which they require access to it. Each researcher who collects data on persons within a research must provide for:

a) separate collection and keeping of collected data and their identification; and
b) timely destruction of identification data.

V In the case data de-identification cannot be assured, personal data must be stored and protected in accordance with the Personal Data Protection Act.

3. Ethical assessment

Ethical assessments are generally needed in any research work involving interaction with people or when it is based on personal data collection. Personal data includes information on behaviour in environments in which individuals can reasonably assume that they are not being watched and data for which individuals can reasonably assume would not be disclosed to the public. The detailed nature of an ethical assessment is determined by specific features of individual research.

Ethical assessments should be guided by the elements listed below:

- the proposed study addresses a substantiated question of research;
- the enrolment of participants is appropriate
  - participants have the ability and are able to freely decide whether to participate;
  - participants are under no pressure to participate;
  - participants have not been offered remuneration in excess of compensation of costs;
  - participants have not been promised unrealistic benefits and advantages;
  - participants have been appropriately presented with the study;
  - the application is enclosed with an example of an appropriate protocol of addressing candidates for the study;
- the method is appropriate
  - the method enables a reply to the posed research question;
  - the process poses no danger to participants;
  - the process does not pose excessive burden on participants;
  - the process does not involve unnecessary or excessive exposure to stress;
  - the process does not involve unnecessary or excessive exposure to offensive or emotionally difficult stimuli and content;
  - the application has been enclosed with an example of appropriate non-standard stimuli or instruments;
- deceit / transparency of research
  - participants have been informed on the actual purpose of the research;
  - the purpose of the research has been suitably presented before its execution;
  - in case the research requires deceit or naive participants, the protocol should include an appropriate debriefing of participants after the completion of the research;
- extraordinary situations
  - in the case of extraordinary situations (identification of a danger or threat to participants or other persons), an appropriate protocol for action has been prepared and enclosed;
- competence of performers

    - persons conducting the research have the appropriate knowledge and competence to perform the study;
    - persons conducting the research have permits to use the proposed instruments;
- informed consent has been suitably obtained
    - the process of obtaining consent has been appropriately set up;
    - the "Statement of the conscious and free consent to participation in the research" featuring all necessary elements has been enclosed;
- personal data protection has been ensured
    - data are stored under codes preventing data identification;
    - the information needed to identify codes are stored separately from the data;
    - an acceptable deadline for data de-identification has been specified;
- the time course of the study is acceptable.

4. Participants

Number and description of participants

The number of participants should be sufficiently large to enable the verification of hypotheses. Due to the possibility of participants terminating participation and the loss of results due to technical reasons, it is permissible to plan work with a slightly higher number of participants than would be necessary; however, it is unacceptable to excessively increase the number of participants. When possible, the substantiation of the planned number of participants should be supported by an appropriate analysis of the strength of the study. The description of participants should clearly specify the planned sample of participants and present inclusion and exclusion criteria for participant selection. The criteria are there to ensure that neither inclusion or exclusion from the possibility of taking part in the research are subject to any unfounded bias or discrimination.

Manner of obtaining participants

Researchers should describe the method for forming a sample and the manner by which participants would be invited to take part in the research. On the one hand, it should be ensured that potentially interested individuals have equal opportunities to take part in the research and on the other hand any form of using force to ensure participation in the research or obtaining participants through deceit should be avoided. Participation in a research project should be in any case a free choice of the individual and a decision based on clearly presented key information on the research.

The assessment of the voluntary nature of participation should consider that force may take various, sometimes difficult to identify, forms. Participants should always be aware that their participation is completely voluntary and that their well-being is in no way dependent on it, in either positive or negative way. Individuals declining to participate in a research project should suffer no negative consequences, explicit or implicit, actual or perceived. Particular attention should be paid to prevent participants agreeing to take part in a research project due to social pressure or pressure from an authority. On the other hand, individuals deciding to take part in a research project should expect no benefit exceeding the knowledge and experience obtained by participation in the research and only minimum compensation for the time and effort spent and reimbursement of costs directly related to participation the research. Any pecuniary award, promise of a higher grade or privileged treatment represent an inappropriate form of inducing participation in a research project.

The description of the manner planned to obtain participants should show how participants would learn of the research, who will address them and what information they will receive on the research. In particular, in situations where there could be a feeling of being forced to participate, a detailed

explanation is needed as to how participants would be assured that their participation is completely voluntary.

Any compensation for participation

By taking part in a research study, participants offer to the researcher their time, energy and good will and in many cases participation results in additional expenses. If possible, participants should be offered an appropriate compensation for the time spent and a reimbursement of costs. Particular care should be paid so that the planned compensation does not exceed actual costs and a reasonable remuneration for time spent. Payments and financial incentives for participation are not acceptable owing to the reasons listed in the previous item hereof.

5. Research plan

It is advisable that researchers prepare a research plan presenting the basic outline of the research. It should describe the number of groups into which participants would be divided, how the groups would differ and which variables (factors and their respective levels) would be controlled and measured. It should also present a schedule of the research featuring information on the planned time needed to a) make preparations, b) obtain participants, and c) analyse data. It should further contain any information on participating organisations and their consent to take part in the research study.

Procedure

The procedure contains a detailed description of the execution of the research task. The content of this section depends on the area of research and the approach used to conduct the research. The most often presented topics are descriptions of instruments and tests used, and instructions to participants.

List of instruments and tools

Here, researchers list all instruments and tools to be used in the research. A brief description and the purpose of its use should be given for each instrument. An appropriate reference document where the instrument is described should be given for standard instruments and tools. In the case of instruments developed by researchers themselves, a detailed description of their content and measurement properties should be included. The listing of instruments should include information on who will use them and information on their qualification to operate the instrument. An assessment of the duration of use of a particular instrument should be provided as well.

Description of experimental tasks and processes

If the research involves the performance of one or several behavioural tests or other experimental tasks or processes, the researcher should describe each of them in this section of the research plan. The description should contain the stimuli and conditions applied, the course of the test, the tasks of participants and the measured variables. The researcher should also include information on the number of tests and any breaks, and an assessment of the entire time that would be needed to conduct the test.

Instructions to participants

In this section, the researcher should describe instructions that would be given for each part of the execution of research. In the case of standardised instructions, they should be added to the research plan as an attachment.

The description of procedure should be concluded by an estimate of the total time necessary for the entire

protocol of the conduct of the research.

6. Consent for participation

Voluntary and informed consent for taking part in a research project is a fundamental ethical principle of scientific research. The key element of its assurance is the *Informed Consent* form, which should be, as a general rule, read and signed by each participant in a scientific research study and/or by his or legal guardian.

The consent of participants is generally confirmed by signature of the *Informed consent for participation in the research* form. The content of the form is described in detail in the document *Informed consent: instructions for preparation*. The task of researchers in this section of the application is to describe the manner in which consent would be obtained; in the case of verbal consent, reasoning for not using consent in writing should be given; in the case of research involving deceit, the process of debriefing after data has been collected should be presented.

Obtaining consent

The task of researchers is to describe how and when participants would be presented, in detail, the research task and other elements covered by informed consent and how participants will be given an opportunity to pose any questions about the purpose of the research and the details of their participation. If possible, it is important that the researcher present the research, responded to questions and obtained consent through personal contact. Indirectly obtaining consent through mail or through teachers or students would be inappropriate as participants and their guardians would be prevented from posing questions and receiving full information on the research before giving consent. When the nature of the research prevents the researcher from personally obtaining consent, the presentation of the research may be entrusted to other persons working on the task, who must be suitably informed on all key elements of the research. In such a case, the person presenting the research will sign the informed consent form.

It is crucial that the process of obtaining consent is focused on actual participants in the research. This also applies to participants who are minors or those with a legal guardian. If the participant can read, he or she should read and sign the informed consent form and the text of the form should be adapted to suit his or her level of comprehension. If the participant is unable to read, the task of the researcher will be to present verbally all key elements of consent and ensure that the participant understands them. The best way to ensure understanding is to ask participants to repeat and present, in their own words, the key elements. Only after participants in a research project have fully understood the purpose of the research, what is expected of them, what will be the benefits and risks of participation and the fact that participation is completely voluntary and may be terminated at any time without consequences and they have accepted to take part, can the consent be signed by their parents or guardians as well.

Omission of consent in writing

In some cases, consent in writing would be undesirable or virtually impossible to obtain. A possible case would be a research project where even the knowledge that an individual has taken part in it would represent an unacceptable level of risk for the participant. An example would be study of sexual behaviour of HIV infected persons. If the appropriate obtaining of verbal consent is ensured, no consent in writing will be needed in such cases.

Research may be conducted in such cases without first obtaining consent statements if the following conditions are met:

- the research does not pose more than a minimum risk to the participant; and
- the rights and well-being of the participant have not been infringed upon.

Another example would be studies where obtaining consent would have a direct effect on research results and prevent examination of the research problem. Example of this would be studies based on observations and/or management of social situations where obtaining informed consent beforehand could fundamentally alter the behaviour of individuals and their group interactions. It is similar for studies where the research plan is based on various forms of deceit and/or requires from participants not to be aware of certain stimuli or an aspect of the research plan. When the research poses no more than minimum risk to participants, critical content can be omitted from the informed consent form or the form itself could be omitted.

Debriefing

In the case of studies where consent form has been omitted or altered due to the requirements of the research plan, a debriefing of participants should be organised after the research is completed in order to inform them of the actual nature of the test and the reasons for omitting consent or using deceit, and their consent to use the collected data should be obtained. The task of the researcher is to present in the application how and when the debriefing would take place and how the consent to use results would be obtained. If debriefing will be made in writing as well, it should be enclosed with the application. When no consent is obtained prior to the collection of results, the consent to use results should be obtained in writing after data collection has been completed. When a consent in writing has been obtained, a verbal consent to use results will be obtained after debriefing and participants should be given an option to opt out of the research. In any case, the procedure should be appropriately presented in the application.