Do I need a license or Review?

TRANSCRIPT

Research Ethics Online Course

1. Introduction – do you need to apply for a license or an ethical review for your research project? This short presentation will help you identify and understand the process and reasons behind licenses and ethical reviews.

2. First a cautionary note. There are significant differences how countries deal with ethical approvals and reviews. Having got the approvals process completed in one country does not mean it will be accepted in another. In international research groups it is essential to discuss how and where approvals are applied. In Finland, the ethical approval process is tightly legislated for biomedical research, but is based on recommendations for all other types of research. In comparison as close as Norway all research involving people is tightly regulated.

3. Information in this presentation is intended for guidance only and if you think you may need an approval or should apply for an ethics review, please examine the additional information closely and discuss the process with your research team. Now let's go through a set of questions that will help you decide you need to apply for a license or a review.

4. Do you work with experimental animals? If yes, an approval and a permit is necessary. In Finland approvals and license for research on animals is typically given to each project with a principal investigator, so you are unlikely to need to go through the process personally, but you might want to have a look at the approvals and licenses in place for your group.

5. Animal research approvals are typically based on estimating a balance of harm and benefit. On the side of harm is any harm experienced by the animals involved. To minimise this harm, all projects are required to prove they have exercised a triple R process: Replace animals whenever possible with other methodologies, Reduce the number of animals to the minimum in order to achieve the research goals and lastly Refine the procedures in a way that they cause minimal harm to the animals. Once the harm side is minimised it is compared with the expected outcomes of the research including any scientific merit, increase of knowledge and potential for application. Only when the two sides have been evaluated is it possible to pass on a judgment whether the benefits outweigh the harm. Those opposing using experimental animals of any kind put forward an argument that no benefit can outweigh the harm

experimental animals experience. Information on the experimental animal licenses is found on the ELLA website, link below.

6. Do you do medical research? That is research, which interferes with the integrity of a person, embryo or fetus for the purposes of learning more about health and illness. This could mean working with patients, human tissues, or medical records. If you say YES, this sounds like my research, you will need an license to do your study. Licenses are granted by the institutions where the research is carried out. For a medical research license, you will need a supportive statement from an ethics committee in the local area for example a University hospital.

7. Ethics committees will look at each research proposal from multiple perspectives: they will consider the scientific merits of the proposal, make sure it done according to relevant Acts, decrees and laws as well as evaluate it on the ethical merits and relevant research values. A supportive statement from the ethics committee is necessary to obtain a license to study.

8. Does your study collect information or material from people, but it is not medical in nature? You will not need a license for your research work, but you may need submit it to preliminary review by an Ethics Committee.

9. First you need to ask: Could my research cause physical, mental, economic or social injury to my subjects? If you think it could, you should submit your proposal to an ethical review. Guidelines specifically highlight the need for an ethical review for the following research designs:

    a. The study involves an intervention in the physical integrity of subjects.

    b. The study deviates from the principle of informed consent (ethical review is not required if the research is based on public documents, registries or archived data).

    c. The subjects are children under the age of 15 and the study is not part of the normal activities of a school or an institution of early childhood education and care and the data are collected without parental consent and without providing the parents or guardians the opportunity to forbid the child from taking part in the study.

    d. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example studies containing violence or pornography).

    e. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life.

f. The study can signify a security risk to subjects (for example studies concerning domestic violence). You will find a link to the Guidelines below.

10. So you will need to submit your proposal to an ethics review committee in your university. It is a good idea to discuss the submission with the committee before submitting to make sure you have all you need for your submission

11. An ethical review committee will then examine your proposal. They will use the guidance from the Finnish Advisory Board on Research Integrity and compare that with your research plan and best practice in the field. The focus will be on voluntary participation and informed consent, avoiding physical, psychological, financial and social harm, and protecting privacy.

12. If the Ethics Committee finds your research as ethically acceptable, it gives a recommendation for the commencement of the research. The committee can also recommend ways to reduce the risk of injury.

13. An unsupportive statement from the committee usually means you need to make changes to your research plan and possibly re-submit it to a review before starting your work. While the Ethics Committee does not give a license, an unfavourable statement is a strong signal from the research community that the research does not adhere to current best practice. If you persisted with the plan, it would be reasonable to expect challenges along the way and great difficulties in publishing your results.

14. Your publisher or sponsor may also require a statement from the Ethics Committee or it may be necessary in international collaborations. It is important to note again that the process of licenses and reviews vary from country to country. In many countries a license is required where in Finland an Ethics Committee statement is sufficient. In such a case, the Ethics Committee statement is what you will need.

15. If in doubt, contact the Ethics Committee in your University and find out if a review is recommended.