Application instructions for ethics reviews

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1. Mission of the Committee

In accordance with a decision made by the chancellor, the mission of the Viikki Campus Research Ethics Committee is:

- To review the ethics of studies conducted on farmed and pet animals, as well as other vertebrates and other animals protected by legislation (cephalopods, foetal forms in mammals and certain larval forms in vertebrates) that fall out of the scope of the Act on the Use of Animals for Experimental Purposes
- To offer consultation in matters relating to research ethics
- To provide advice for solving research ethics problems on the campus

A further definition of the Committee’s duties:

- Assessing the ethics of medical and non-medical research on human subjects, as well as studies under the scope of the Act on the Use of Animals for Experimental Purposes falls outside the Committee’s mandate.

2. Applying for an ethics review from the Committee

2.1 Studies to be reviewed

Opinions on the ethics of research can be requested from the Viikki Campus Research Ethics Committee for the following study types:

- Research on vertebrates (human subjects excluded) and/or cephalopods. Investigators may also apply for reviews of studies conducted on other species.
- Research that falls outside the scope of the Act on the Use of Animals for Experimental Purposes. In other words, the discomfort that the animals are subjected to is less than that caused by a needle prick. Studies that cause discomfort equal to or larger than a needle prick fall within the purview of the National Animal Experiment Board ELLA: http://www.laaninhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/pages/indexing. However,
studies that cause discomfort equal to or larger than a needle prick as part of regular treatment procedures can be reviewed by the Viikki Campus Research Ethics Committee.

- Scientifically peer-reviewed research
  - Opinions can also be requested for Master’s theses or doctoral dissertations. In such cases, applications are to be submitted by the supervisor together with the student.
- Research implemented by researchers or students of the University of Helsinki

Does reviewing my survey fall within the purview of the Viikki Campus Research Ethics Committee or the Ethics Review Board in the Humanities and Social and Behavioural Sciences?

- Occasionally, information on animal subjects is collected through surveys targeted at animal owners. In these cases, the nature of the research is based on both human and animal sciences. For these studies, a single opinion from one of the two ethics committees will suffice. If surveys are used to gather information only on animal subjects and/or if the study includes the examination of animal subjects with other methods (e.g., sample collection, dietary changes, etc.), ethics review applications are to be submitted to the Viikki Campus Research Ethics Committee. When the sole purpose of a survey is to gather information on animal owners (for example, surveys focused on the owners’ methods for treating their animals, the significance of animals to their owners, etc.), opinions will be requested from the Ethics Review Board in the Humanities and Social and Behavioural Sciences. When necessary, the committees will support each other in reviewing the ethics of studies that fall in between these two categories. If uncertain of the committee to which the application is to be submitted, please ask for advice from the committee secretary at eettinen-toimikunta@helsinki.fi. In reviewing study elements related to human subjects, the committees observe the ethical principles of the National Advisory Board on Research Ethics.

2.2. Application schedule for ethics reviews

Applications for research ethics reviews must be submitted before study implementation.

- For special and well-grounded reasons studies can be reviewed retroactively. If a retroactive review is required, please contact the committee secretary in good time for further instructions.

Review applications to be examined in committee meetings should be sent by email to the committee secretary at eettinen-toimikunta@helsinki.fi. Applications for ethics reviews, including all necessary attachments, must be sent as a single PDF document no later than two weeks prior to the meeting in questions.

The Committee will review the application in its meeting and make a decision to either give an opinion on research ethics or to ask further clarification or supplementary information from the investigator. Opinions or requests for supplementary information will be sent to investigators by email within two weeks of the meeting.

- Requests for supplementary information should be answered as soon as possible. Minor supplements to applications will be reviewed in an expedited manner before the next meeting. More substantial supplements demonstrating a change in the experimental setting significant to research ethics will be examined at the next committee meeting.
2.3 Drafting a review application

Language of application

- Applications may be written in Finnish, Swedish or English.
- Material to be given to animal owners must be drafted in a language that they understand.

Application sections

1. Cover letter for the Committee
2. Brief research proposal
3. Principal investigator’s personal assessment of the ethics of the study
4. Information sheet and consent form for the owner of the subject animal
5. Other written material to be given to the animal owner
6. Privacy Notice of the Scientific Research

Below are more detailed instructions for drafting these sections.

2.3.1 Cover letter for the Committee

The cover letter must contain at least the following details:

- Title of the study
- Unit of research
- Start and end dates of the study
- Persons applying for the ethics review and their affiliation with the University of Helsinki
- Grounds for the application, such as
  - The funding agency or cooperation partner requires a review by an ethics committee.
  - Research results are to be published in journals that require an ethics review.
  - The researchers wish to obtain an opinion from the ethics committee to support their deliberations.
  - Other reason, please specify.

2.3.2 Brief research proposal

The proposal, no longer than three pages, is a concise and clear description of the study. Abbreviations and field-specific jargon should be avoided. The research proposal is scientifically grounded by referring to the most important prior studies supporting the proposal.

A brief research proposal includes at least the following information:

- Background, purpose, objectives and significance of the study
  - In a drug trial, basic information on the pharmacological properties of the active ingredient (e.g., drug category)
- Research design and methods
- Additionally, information on the permits required for the study (parties granting the permits, permit codes and validity)

- Study progress and description of procedures, such as
  - Number of animals and inclusion criteria for sampling (e.g., species/breed, age, health, etc.)
  - Concrete procedures that animals will be subjected to and how they differ from the regular handling and/or treatment practices
  - Number of research or evaluation visits for individual animals
  - Duration of procedures/evaluation/interviews for each individual participant

### 2.3.3 Investigator's personal assessment of the ethics of the study

In their personal assessment, the principal investigator must consider, among other things, the research data collection method, the study implementation method, the manner in which subject animal owners are provided with information, and the plan for handling and protecting data related to animal owners from the perspective of risks and damages. The assessment must weigh up potential adverse effects and inconveniences caused by study participation to animals or animal owners in relation to the desired knowledge value of the study and potential benefits for participating animals. Study ethics can be reviewed also from wider perspectives, for example from the perspective of society or environmental protection.

The assessment must consider and justify at least the following factors:

- How will the study observe the 3R principle (Replacement, Reduction, Refinement)? Why will the study be conducted on animals and the species/breed in question? How is the number of required animals justified? How are the risks and adverse effects caused by the study minimised? Why is the research design in its entirety the best option for obtaining the desired results?
- What are the primary inclusion and exclusion criteria for individual animals? Are there special groups, such as newborn, old or sick animals, or rare species, among the study participants?
- Should any procedures be conducted on animals, their foreseeable risks, benefits, adverse effects and discomforts must be assessed, for example in comparison with regular treatment visits.
- Should any participating animals be put down, relevant criteria must be assessed and justification must be given. Are there alternatives to putting animals down and if there are, why are these not utilised? This item requires special attention when putting down animals is a routine procedure in the research proposal, not only a last resort in emergencies.
- If the investigative product is medicinal, its safety and efficacy must be assessed on the basis of information collected so far (please describe briefly the results of prior, relevant studies and adverse effects). Potential requirement for an advance notification for clinical trials on veterinary medicinal products from the Finnish Medicines Agency Fimea must be verified: [http://www.fimea.fi/web/en/veterinary/clinical_trials_on_veterinary_medicinal_products](http://www.fimea.fi/web/en/veterinary/clinical_trials_on_veterinary_medicinal_products).
- If the investigative product is not medicinal (e.g., food additives), its safety must be assessed on the basis of scientifically peer-reviewed research data collected so far.
- If a placebo or control compound is used in the study, its use must be assessed and justified. What risks and adverse effects can lack of treatment cause and how will potential adverse events be handled? This should be considered also in the event animals are used to test a
procedure on whose safety and efficacy there is no consensus due to lack of extensive and applicable scientific research.

- If personal data will be collected during the study, a description of data management and protection must be provided. It is recommended to read the privacy section of the Ethical Principles of Research in the Humanities and Social and Behavioural Sciences: http://www.tenk.fi/en/ethical-review-in-human-sciences#3
- Have animal owners been provided with appropriate information before giving their consent?

2.3.4 Information sheet and consent form for the owner of the subject animal

The information sheet should include all relevant information about the study that the subject animal owner needs to give informed consent for participation.

The following study details will be described in a concrete manner and in layman's terms:

- Name of the person in charge of the study, the background organisation and the sponsor
- Funding agents and cooperation partners, including their role in the study
- Name and telephone number of the contact person (when necessary, also outside office hours) for further information, adverse events and emergencies
- Topic, purpose and objective of the study, as well as its significance in the specific field
- Unit of research, study dates, duration and type (one-off or follow-up study)
- Approximate total number of subject animals, and primary inclusion and exclusion criteria
- Research data to be collected (e.g., observations, samples, measurements, photographs, tests, surveys)
- Effects of study participation on the everyday life of the animal and its owner (observation, special diets, physical activity and other effects) and what is expected of the participants
- Potential benefits or discomforts caused to the animal's health by study participation and their likelihood (for example, compared with regular equivalent treatment procedures)
- The manner in which study risks have been minimised and preparations made in case risks are realised, procedures to be followed in the event adverse effects occur
- Methods of use for the research data (including scientific journals and popular communications)
- Methods of securing the confidentiality of personal data (for example, by anonymisation)
- Handling of data collected up to the point of discontinuing study participation, should that occur
- Archiving data and/or leftover samples for the purposes of further research or teaching, including archiving destination
- Any compensation for participation or cost reimbursements/price reductions offered to participants

As a rule, the consent form is no more than one page in length, but it should contain a summary of all relevant elements for which a written consent is required:

- Title of the study, those involved in the study, name of the researcher and the principal investigator, name of the animal's owner, name of the animal and any other necessary
identifying general description (e.g., species, breed, age, gender), name of the person who provides information orally to the animal owner, place, date and signatures

- Expression of consent for study participation
- Notification of providing the owner with a description of the study in accordance with the information sheet both orally and in writing, as well as with an opportunity to ask questions and receive answers to them
- Voluntary nature of study participation, participant’s right to ask further information about the study and the right to discontinue participation without having to provide a reason and without any repercussions at any stage of the study

2.3.5. Other material given to the animal owner

- Survey forms
- Interview structure/themes
- Instructions and descriptions on, for example, diets/devices to be used during the study

2.3.6. Privacy Notice of the Scientific Research

If personal data is processed in the study, please read Data Protection Guide for Researchers: https://flamma.helsinki.fi/en/HY375934, and the Privacy Notice of the Scientific Research.

The researcher can fill in the Privacy Notice of the Scientific Research and attach it to his / her application, or include the information mentioned in the Privacy Notice, as appropriate, in sections 2.3.3. - 2.3.5.