

# **Ethical vetting of research involving humans**

## **Guidance to the application**

This information is in addition to the instructions that can be found on application form VRFS 2009:1 (the application form)

### **Particular information**

When any changes are made to an application that has previously been approved, the applicant must submit a letter detailing what changes have been made and explaining the reasons for them.

Together with the letter should be sent any relevant documents concerning the changes (certificates, alteration of protocols etc). If changes are made in the protocols or any other document previously submitted, these changes are to be marked so that it is clear what changes have been made.

If the study was approved prior to 1 January 2004, the previously approved application, together with the approval granted, is to be submitted. In such a case, the relevant parts of the new application form are also to be filled in, (references may be made to the previous application that is enclosed). This should then be signed.

What constitutes an important change is to be decided on a case-by-case basis (see proposition 2002/03:50 pages 115-116). By way of example: the inclusion of more research subjects (with the same characteristics); the involvement of more units recruiting research subjects; new analyses to be carried out of material already collected where the issue being dealt with is essentially the same; or suspected new side-effects that can require special measures to be taken.

If a change to the original project is extensive (i.e. a new design for the study or studies of new groups of research subjects with different characteristics than the original ones) an entirely new application is to be submitted.

### **1:1 The entity principally responsible for the research**

When research is conducted under the auspices of a university clinic, both the county council and the university may be deemed the responsible research body, if the researcher who is carrying out the study is employed by either the university or the county council. The deciding factor should be if the research is primarily carried out as part of the researcher's work as an employee of the county council or as an employee of the university. When the research is carried out as an assignment, the responsible research body is the body who has undertaken to conduct the research.

### **1:3 Researchers who are primarily responsible for the conduct of the project (principal contact person)**

When work is being carried out by doctoral candidates or other students, the researcher who bears the main responsibility for the conduct of a project will be the principal supervisor, as a rule. It is the qualifications and competence of this person that should therefore be stated, in accordance with point 9 of annex 10. There is nothing to prevent a doctoral candidate from being the contact person in addition to the principal supervisor. When research is carried out on behalf of someone else, the primary responsibility will be that of the researcher who has been given the task of being primarily responsible for the conduct of the study under the auspices of the body principally responsible for the research. If several responsible research bodies are involved, or if several researchers within the same county council are cooperating on the same project, one researcher is to be appointed the principal investigator, who is then the contact person with respect to the ethical vetting board. This naturally does not preclude others working on the project from acting as contacts for specific purposes (for questions from the research subjects, the Swedish Data Inspection Board, the Swedish Radiation Protection Authority etc.) Where multi-centre studies are concerned (see point 1:4 of the application and this guidance) it is the responsibility of the principal researcher when this occurs to ensure that the competence is documented of every researcher responsible at each participating clinic, centre, etc. (see point 1:5 in this application and also this guidance).

### **1:4 Location**

This is where to list places in Sweden where some kind of measure immediately linked to the research subjects take place. This applies even if the project is undertaken at several institutions where for example care is administered under the auspices of the same responsible research body. If it is simply a case of samples being sent to various places for analysis, there is no need to list them here.

### **2:4 Give an overview of the examination procedures used, data collection and the nature of the data**

If the project is part of an international collaboration, that part of the research that is carried out in Sweden is to be subject to ethical vetting in Sweden. A description of the entire project is still required.

## **2:5 Describe how biological material that has been collected is to be stored in a biobank**

Samples that are to be saved for a specific research project or for a future project as yet unspecified are to be kept, analysed and otherwise dealt with so that the integrity of the sample donor is protected. The routines for storage, whether or not this is under the auspices of the health-care services, and the procedures for analysis or distribution to another responsible research body for research are to be described in a manner clearly showing whether or not samples can be traced to particular individuals. If the samples can be traced, the method used should be clearly stated. For example: if the donor's identity can be traced by means of a key to a code that is in the possession of the researcher; if the key to the code is in the possession of someone other than the researcher; or if the samples are marked so as to reveal the donor's identity directly. If the samples are not marked in a way that reveals the donor's identity, the method used for marking should be indicated - for example: consecutive or random number or letter codes. It should also be clearly stated if it is intended to keep the samples for a certain period of time or an unspecified time and for what kind of usage in the future they are being kept.

Similarly, if samples are to be taken from an existing biobank, the terms under which they are to be released to the researcher should be clearly stated (if, for example, the samples are to be returned or destroyed after analysis). There must be a description of how samples are to be stored once they have been issued and how they are traceable to the donor. For samples collected under the auspices of the health and medical services, the Biobanks in Medical Care Act (2002:297) is applicable.

## **2:7 Record-keeping, registering and processing of data**

The ethical vetting also entails establishing whether any treatment of personal data as part of the project is done in accordance with the provisions of the Personal Data Act (1998:204). By personal data is meant any and all information that can directly or indirectly be traced to a living physical person. By treatment of personal data is meant any measure or series of measures taken with respect to personal data, whether or not this is done automatically. All such treatment of personal data to be carried out in the project and that might be of significance for ethical vetting is to be described. Indicate traceability in accordance with point 2:5 above.

## **3:1 How are participants in the research chosen?**

The delimiting of the population studies is to be clearly related to the scientific issue(s) specified in point 2:2.

**3:3 State the statistical foundation with respect to the size of the population(s) and/or material(s) studied**

Ethical vetting entails an evaluation as to whether the purpose of the project can be achieved by means of the chosen methodology. For quantitative studies the statistical basis should therefore be described in such a way as to establish that the basis is sufficient to provide an answer with respect to the principal issue, but is not unnecessarily large. For qualitative research, the choice of method and the number of research subjects should be motivated in the same way. In those cases where explicit hypotheses (whether primary or secondary) are to be tested, it should be clear under what circumstances a hypothesis would be rejected.

**3:4 State if participants in the research may be included in several studies either simultaneously or in other study or other studies closely linked to this one. If so, what kind of research?**

The responsible research body should ensure that participants in the research are not simultaneously being offered participation in several studies, if it is possible that the combined risk this entails is greater than the risk of participation in each individual project.

**3:6 What financial remuneration or other benefits are participants in the research entitled to and when is this to be paid?**

Over and above compensation for travel, loss of income or other expenses, participants in the research may be entitled to some compensation for any discomfort and inconvenience. This compensation is to be reasonable. If children or young people (younger than 18 years old) participate in the project, such compensation is not to be a large amount and should not be proffered at the time of recruitment. When clinical trials of medicinal products are carried out on children (under the age of 18), no inducements or financial benefits are to be given, with the exception of compensation for expenses.

**4:1 The procedure involved and the content of the *information* that is given when subjects are asked to participate in the research**

Click on the following link: [Information for research participants](#)

**4:2 How is consent to be obtained and from whom?**

Click on the following link: [Information for research participants](#)

**6:1 How are both the person principally responsible for the research and research collaborators guaranteed access to data (to be stated when the research is an assignment) and who is responsible for processing data and writing reports?**

If several researchers are collaborating on research that has been assigned to them, the researcher who is principally responsible for the conduct of the research should reach an agreement in advance with other researchers about access to data.

**9. List of annexes**

Appendices to the application for ethical vetting should be attached unless corresponding information is on the form. However, a research plan/protocol for specialists should always be attached. References may be made on the form to such a detailed plan or protocol. The research plan/protocol is primarily the basis for the member of the board who is to present the case to the board and it may be written in English.

Permits from the Swedish Radiation Protection Authority or corresponding body (point 1:6 and point 9 - other annexes) – if examinations are carried out at several institutions where care is administered, permits are to be obtained from the appropriate radiation protection board