

# Frequently Asked Questions

## Basics

**I plan on doing research that involves working with people. Do I need an ECRFSS opinion on it?**

The answer to the question depends on several different factors. The simple answer is that you need it if anyone asks you to obtain it, otherwise you don't need it. This, of course, poses the question of who is entitled to require an ethics review and opinion of the ECRFSS?

### *Slovenian legislation*

The Slovenian legislation for empirical research in the social sciences does not require ethics review and it is therefore not required for the conduct of research work. However, the legislation sets out some important requirements regarding the protection of personal data. In short: firstly, it requires that you obtain appropriate consent from participants for the collection and use of their personal information, secondly, it requires that the data be properly protected and used only for agreed purposes, and thirdly, it requires that at the end of the survey the data be adequately de-identified by destroying information about who the individual data belongs to.

### *University of Ljubljana*

For several years, the University of Ljubljana requires that dispositions of doctoral dissertations involving research work with people should also be accompanied by appropriate ethics review of the proposed research work. The review must be attached to the disposition at the latest when the disposition is to be assessed by the University Senate. Dispositions without proper ethics review are returned to the faculty with a request for ethics review.

### *Scientific journals*

In scientific journals that publish empirical articles, an appropriate ethics review of the research work presented is increasingly becoming one of the conditions for publication. Most journals only require that participants give their informed consent to participate in the survey. However, more and more journals are also requesting confirmation that the research has received appropriate ethics review.

### *Foreign research institutions*

The legislation defining the conditions under which research work can be carried out is much stricter in some foreign countries than in Slovenia. It often defines that any research that involves research work with people should receive appropriate review of ethical aspects. Each scientific research organization is required to set up an ethics committee to verify the ethical adequacy of the planned research work, and compliance with the legislation is regularly checked by inspection services. It is a common legal requirement that the comparable protection of participants' rights is ensured by all foreign partners with which organizations participate in international research projects. If, for example, you are planning a research collaboration with a US university, it is your US partner's responsibility to ensure that the research in Slovenia receives the appropriate ethics review.

### *Slovenian Research Agency (SRA)*

Calls for proposals (co-financed by SRA) require the approval<sup>1</sup> of an ethics committee to carry out certain research projects. This requirement currently applies to the call for proposals for basic,

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<sup>1</sup> This is a summary of the SRA diction, it concerns the assessment of ECR.

applied and postdoctoral projects as well as targeted research projects. An ECRFSS approval must be obtained if the applicant indicates in the tender dossier that the proposed research raises sensitive ethical issues related to humans, human biological samples, personal data, genetic information or animals. This opinion should also be obtained in the following cases:

- research aimed at human cloning for the purpose of reproduction
- research aimed at changing the human genetic heritage
- research aimed at creating a human embryo solely for the purpose of researching or at acquiring a stem cell.

In the case of calls for basic, applied and postdoctoral projects, this issue should be addressed in the second phase of the project application, while for CRP calls this should be indicated immediately in the application form. The request for approval that should be issued by ECRFSS must be checked on a case-by-case basis. Applicants will be specifically alerted to this request already by the relevant professional service.

### **When exactly do I need an ECRFSS opinion?**

You will probably need an ECRFSS opinion in the following cases:

- when dealing with sensitive data or vulnerable groups
- when planning a research for a doctoral or other research assignment,
- when planning a research whose findings you would like to publish in a recognized international journal,
- when planning a research in cooperation with foreign partners from countries with stricter legislation,
- when applying for a research project with SRA,
- when the client or the funder requires it,

when the research involves research work with people.

### **Informed consent**

**The instructions state that a prepared statement of informed consent must be attached to the application for ethics review. Does this mean that I have to collect the consent of all the participants before I submit the application?**

**By all means no!** The ECRFSS does not collect signed informed consent forms and does not need them for ethics review. By unnecessarily submitting signed forms, you are violating ethical principles by revealing to third parties who participated in your research. Prior to collecting consents, you must submit the proposal of the form for obtaining informed consent to the ECRFSS for review. The ECRFSS assesses whether the prepared form complies with ethical principles and standards, proposes amendments and supplements, and approves the form. Only after the ECRFSS validates the form can you begin collecting the participants' consent.

### **The procedure of the review**

**Who submits the application for ethics review?**

The application for ethics review is submitted by the researcher in agreement with the principal investigator. In the case of a doctoral thesis, the application for ethical judgment is submitted by the doctoral candidate in agreement and with the knowledge of his or her mentor. The mentor is obliged to review the application and give his or her consent before submitting it for review. The doctoral candidate is also required to consult the mentor about any changes and additions to the application and submit them with the mentor's knowledge and consent.

#### **What is the deadline for considering an application for ethics review?**

In case of a properly prepared application and the normal circumstances of the ECRFSS, you can expect a response no later than thirty days after you submit your application. However, the time necessary for the review may be extended in the following cases:

- an increased load of the ECRFSS with a larger than usual number of applications submitted,
- the need for major changes to the application,
- ethical sensitivity or controversy of the proposed research.

For the smooth conduct of the research work, it is advisable to submit an application for ethics review two months before the scheduled start of the research. Due to the cyclical nature of doctoral studies, it is advisable to submit an application for ethics review of your doctoral research work by 1 June if you wish to obtain the review by 1 September of that year.

#### **How can I contribute to a faster review procedure?**

Before submitting, you should familiarize yourself with the instructions for preparing the application and the informed consent form. Doctoral students should consult with their mentor before submission. Make sure that all required content is properly addressed in the application. Use the prepared samples on the ECRFSS website when submitting the application and preparing the form.

#### **What is the cost of examining an ethics review application?**

For all members of the Faculty of Social Sciences (students and employees), ethics review of research project proposals is free of charge.