

# **Advice from Switzerland's ethics committees on registries, biobanks, and research projects in accordance with art. 51 of the Human Research Act**

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Since early June, researchers can use a new dedicated form in BASEC (Business Administration System for Ethics Committees) to ask the Swiss ethics committees (ECs) for advice on or preliminary examinations of data registries, biobanks, and research projects carried out abroad or any other topics not subject to the Human Research Act (HRA).

For data registries and biobanks, this can ensure, among other things, that data protection is correctly maintained and that research participants' consent is obtained in accordance with legal and ethical requirements. The creation of data registries or biobanks is not formally subject to authorisation under the HRA, but projects that reuse the data and biological samples must generally be approved by an EC. When reviewing data registries or biobanks, ECs focus on compliance with regulatory requirements, the technical aspects of data protection, and ethical implications – for example, the procedure used for obtaining informed consent or general consent.

The aim of preliminary examinations is to make the subsequent approval process go more smoothly for all projects arising from these data registries or biobanks. A preliminary examination will also save an investigational site both time and resources, because generally a site needs to obtain a preliminary examination of a data registry or biobank only once.<sup>1</sup> Moreover, it will save time for all future submissions of research projects. In fact, in BASEC it is possible to link future submissions of research projects to a data registry or biobank that already has a positive preliminary examination.

Obtaining advice or a preliminary examination is voluntary. It is an advisory function of the ECs according to art. 51 of the HRA, and it is invoiced based on ECs' time and efforts. A detailed procedure to obtain advice or a preliminary examination is outlined in a dedicated FAQ, while the documents to be submitted via BASEC can be found in the BASEC portal (see the form Advice on Ethical Questions/Comments on Research Projects Not Subject to the HRA).

This new form in BASEC must be used exclusively to obtain advice or a preliminary examination and should not be used to submit a Clarification of Responsibilities form. A Clarifications of Responsibilities form

(*Zuständigkeitsabklärung* in German, *Clarification des compétences* in French, and *Esame della competenza* in Italian) is submitted to an EC to clarify whether a research project falls within the scope of the HRA and/or request a written statement from an EC if a research project does not need EC approval. However, it is not used to obtain advice on or a preliminary examination of a research project.

The swissethics [website](#) provides information, guidelines, and templates for data registries and biobanks.

1. Unless the data registry or biobank undergoes significant changes or there are legal or regulatory changes.