Guide to submitting additional documents

Guidance material of the Research Ethics Committee

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This guidance explains in which cases additional documents should be attached to a Research Ethics Committee application. The guidance provides explanations by document type, as these are presented on the “Additional documents” section under the „Files“ tab of the application form.

General formatting requirements

To ensure clarity and traceability, please submit all attachments in a consistent and clear format. Each document should have a title and, where possible, a version number and date (or the label “final” if versioning is not used). File names should be clear and should indicate the study acronym, document type, language (where applicable), and version/date. Where several files form a set (e.g., multiple information sheets or consent forms), please keep numbering consistent across files and within the documents, and attach the final versions that correspond to the description provided in the application form.

Recommendations:

- File name format: StudyAcronym_DocumentType_Language_VersionOrDate (e.g., ABC_InfoSheet_ET_v2_2026-04-15).
- If there are several related files, add a sequence number: ..._01, ..._02.
- If a document is updated after submission, keep the same base name and change only the version/date.
- Where feasible, submit documents as searchable text (not scanned images) and include page numbers in longer documents.

1) Study invitation or other participant recruitment information materials

This type of additional document includes all information materials directed at potential participants, except consent forms. The most common example is a study invitation used to invite participants to take part in the study.

The document is required for any study in which invitations or advertisements are used for recruitment. For example:

- the study invitation is distributed via institutional mailing lists;
- the study invitation is sent to participants’ personal email addresses;
- the study invitation is shared in social media groups;
- the study invitation is published as an advertisement in a newspaper or online.

The document does not need to be attached to the application if no recruitment takes place.

2) List of data fields or data table structure

This document type includes all overviews of personal data used in the study that contain a list or summaries of categories of personal data or variables/attributes. As different research fields, and also different data controllers, may have different practices, requirements, or formats for describing the data fields, the Research Ethics Committee does not have a single standard for the data field list.

This additional document is mandatory if, within the scope of the study, personal data are processed without the data subject's consent (IKS § 6). Otherwise, the Research Ethics Committee cannot assess compliance with the requirements of § 6 of the Personal Data Protection Act (IKS).

The additional document is required in the following cases:

- personal data from national databases or registers are used in the study;
- personal data are obtained from other institutions;
- personal data collected in the course of previous studies are used in the study;
- personal data from multiple sources are linked/combined.

A data field list is not required for studies where all personal data processing is based on consent, and all personal data are obtained directly from the individual.

This document may also be provided in the form of a data dictionary.

3) Research participant information and informed consent forms

This document type includes the information sheet provided to the research participant and the consent form. Depending on the study, the information sheet and the consent form may be either combined in one document or provided as two separate documents. In some studies, several different information sheets and consent forms may be necessary, for example one for children in language they can understand and another for the parent. The consent form and the information sheet are not the same as a study invitation, because when consent is requested the research participant must receive much more information about participation in the study.

The consent form has several mandatory components that must be taken into account. A simple overview of the requirements for consent is provided in Chapter 2.3. „What must the consent include?“. The Research Ethics Committee assesses to what extent the consent form is understandable for the person and whether all essential information is presented in it.

Participant-facing documents should be provided in the language(s) used with research participants. In addition, when informing the person and requesting consent, the following should be clearly distinguished or explicitly set out:

1) consent to participate in the study and to any associated burden or risks;
2) consent to the collection of the research participant's personal data and their further processing;
3) additional queries about the research participant, carried out with their consent, to other datasets or databases;
4) consent to the collection of biological material from the research participant and its further use;
5) use of the research participant's contact details during the study and after it (e.g., recruitment to follow-up studies);
6) the right to withdraw consent without consequences;
7) whom the research participant may contact for questions about the study.

Preferably, these aspects should be presented as separate items in the consent form. Where the study design allows, the research participant should be given the option to consent to only some of the aspects listed.

In the case of **proxy consent**, where consent is given by the research participant's legally authorized representative, or by a parent in the case of a minor research participant, it should be kept in mind that proxy consent does not replace the research participant's informed consent, as the research participant themself must also be informed. For example, in research involving children, information should generally also be provided to the children, but it must be understandable in an age-appropriate way. The researcher must also ensure that the child does not participate in the study against their will or under coercion.

When using proxy consent, the information provided to the person giving proxy consent and the information provided to the research participant themself should be clearly distinguished—these should be attached to the application as separate documents.

The consent form and the information sheet must always be attached to the application whenever the study, or any part of it, is based on a person's consent.

4) Research instruments used in the study

This category covers descriptions of all tools used to collect data from people. As a general principle, descriptions of all instruments used to collect personal data should be attached to the application. For example:

- questionnaire;
- interview guide or list of questions;
- descriptions of tests and measurement tools;

- study plans or descriptions of experiments;
- an application or digital tool used in the study;
- descriptions of tasks given to research participants during the study.

The need to submit this additional document arises primarily from practical reasons, as it is not possible to include the content of extensive standardized instruments or their descriptions in the application form. Instruments should be described to the extent necessary to assess participant burden, risks, and data collected. If the method used to collect data from people is not formally structured (e.g., ethnographic observations), this should still be indicated in the application and the method should be described in general terms. If there is uncertainty about whether to submit a research instrument description as a separate document or to describe it in the application form, a threshold of two paragraphs may be used—if the description is limited to up to two paragraphs of text, it may be included in the application form and no separate document is required.

The description and level of detail of an instrument used in the study may change over time. The description should reflect the state of readiness at the time the application is submitted. If necessary, descriptions of research instruments can be supplemented by submitting an amendment request to the Research Ethics Committee.

5) Study protocol or outline

A study protocol or outline is a complete structured description of the study design, methodology, and the procedures carried out with research participants. Whether a protocol or outline needs to be attached to the application depends on the study field and the scale of the study. In particular, protocol is required for clinical trials and for studies in the fields of biomedicine and medical sciences.

A study protocol should be submitted with the application if:

- the study has multiple stages or different research phases;
- the study has a complex methodology that combines different approaches;
- the study is an international study, or involves multiple partner institutions or study sites/centres;
- the study involves interventions or time-structured procedures.

For smaller-scale studies where the description provided in the application form is sufficient, there is no need to submit a separate study protocol. For example, a separate protocol is not necessary if the study is limited to a single round of a questionnaire or interviews and a description of the instrument used has been attached to the application. However, the application form description must still allow assessment of participant procedures and risks.

6) Data protection impact assessment

A data protection impact assessment (data protection impact assessment) should be attached only if it is mandatory for the planned study. Under Article 35(1) of the General Data Protection Regulation, a DPIA is mandatory where the planned processing of personal data is likely to result in a high risk to the rights of research participants.

A DPIA is usually needed where the study processes large volumes of sensitive data, links different datasets, or uses novel or complex data processing methods. The personal data tab in the application form includes screening questions on the presence of data protection risks—if the final question asks about carrying out a DPIA, this means that the application form includes at least two aspects indicating high risk.

Carrying out a DPIA is the responsibility of the controller. If there is any doubt as to whether a DPIA is necessary, you should consult your institution's data protection officer (DPO).

If the DPIA has been classified as confidential by the institution, it is sufficient to submit, as an additional document, a confirmation from the institution that the DPIA has been carried out and that the risks are acceptable.

7) Insurance policy

The document should be attached only if an insurance policy is required for the study and the policy has been issued by the time the application is submitted.

8) Cover letter (amendment request)

Under this document type, attach the cover letter submitted with an amendment request, explaining why the changes to the application are necessary. The cover letter is required only if this is an amendment request.

9) Cover letter (supplementary information)

Under this document type, attach a cover letter addressing how the supplementary information or corrections requested by the subcommittee have been incorporated. The cover letter is required only if the application has been supplemented on the basis of feedback from the subcommittee.

When submitting a new application, this document type is not needed.

10) Researchers' CVs

Under this document type, attach the CVs of members of the research team if a specific researcher does not have an ETIS account or if they have chosen not to make their CV public in ETIS. If a researcher has an ETIS account and their CV is public, it does not need to be attached as a separate file.

11) Data management plan

A data management plan (DMP) is a structured description of how research data will be handled during and after the study (e.g., storage, access management, security measures, retention, and, where applicable, sharing or re-use).

This document should be attached when the study's data management arrangements cannot reasonably be described in the application form within two paragraphs, or when data management is sufficiently complex to warrant a separate plan. If the data management arrangements are straightforward and can be described briefly in the application, there is no need to attach a separate plan. A DMP should be attached to the application, for example, when:

- the study involves multiple partner institutions, study sites/centres, or external service providers, and responsibilities for data handling must be clearly allocated;
- multiple datasets will be combined/linked, or data management includes non-trivial processing workflows that are difficult to describe briefly;
- the study includes long-term storage, planned re-use, secondary use, or planned sharing of data (including deposit in a repository);
- data security arrangements require a more detailed explanation (e.g., use of non-EU platforms/cloud services, complex access control, or multi-step pseudonymisation/anonymisation workflows).

The DMP may be brief and proportionate to the study (e.g., a concise plan focusing on the key points listed above) and should reflect the state of readiness at the time of submission. Where relevant, existing funder or institutional templates may be used.

12) Other document

This document type should be selected if none of the categories listed above is suitable. Examples include confirmation or coordination letters from other institutions, a data management plan, authorizations, or other explanatory supporting materials.