DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Information Sheet for DZHK Ethics Documents

Monika Kraus, 17/02/2017

The DZHK's mission is to promote translation. To complete this mission and to allow for further research in the biomedical sector, the DZHK decided to build a standardised high-quality data and biomaterial collection with the data and biomaterials acquired within the studies. For this purpose, the scientific infrastructure was implemented and has to be used by all DZHK studies.

This infrastructure is comprised of the Central Data Management with the Trusted Third Party, the Data Handling unit, the Transfer Office, the IT Lab (management of biological material, laboratory information and management system (LIMS)), the Image Data Management System (IDMS), and the **Ethics Project**.

What are the tasks of the DZHK Ethics Project?

The Ethics Project support you with all questions regarding your study's ethics documents.
The Ethics Project's main task is **to describe the scientific infrastructure correctly and appropriately in the patient information sheet(s) and informed consent form(s)** as well as to enable the re-use use of data and biological materials by other biomedical research projects. This results in a close collaboration with the Independent Trusted Third Party regarding the content and administrative formatting of the documents to enable its implementation into the IT system.

This leads to following tasks performed in collaboration with the studies:

- Maintaining and versioning of ethics documents
- Archiving of the (central and local) ethics votes provided by the studies to allow for harmonised revision, if applicable
- Support with the submission of ethics documents, and if required, correspondence with the ethics committees (national)
- If required: Support in communicating or coordinating support with (international) CRO(s) regarding ethical aspects (e.g. creating a request paper, support with discussions regarding harmonisation options)
- If required: Study staff training regarding the handling of ethics documents
- If required: Support with organisation of internal audits (regarding ethics documents)

What are the regulations for funding these services?

As the working hours that are required for an individual study are difficult to estimate and rather limited, the Project receives basic funding from the DZHK. Project-specific calculation of cost for this service is not required within the application. Each study will be supported as required.

When should I contact the Ethics Project?

To ensure smooth processing, it is advisable to contact the Project

- **PRIOR to submission of the study to the leading ethics committee.**
- The following information on the study design and use of the DZHK infrastructure is important for us:
  - Which regulations need to be observed for the study? German Medicinal Products Act (AMG), German Medical Devices Act (MPG), (European Medicines Agency [EMA]?), professional code of conduct (BO)
  - Which are the targeted patient populations (elderly, minors, persons incapable of providing consent, …)?
  - Will the study include several arms? Randomisation? Does it include a register? Other information?
  - To what extent will the individual components of the infrastructure be used (data collection /assessments / eCRF content, biobanking (see below), image data management)?
  - Will biomaterial be collected within the scope of the study? What materials will be required and at what volumes? Study biobanking (what kind?) and basic biobanking (mandatory)? Will biomaterial for routine laboratory testing be required?

What will the further process be once I have contacted the Ethics Project?

The first step of communication will usually be an email or telephone call (see below for contact).

The following information will then be required to process your request:

- Complete study application
- Potential additional information regarding scope of biobanking within the study
- (If already available) Study protocol / draft of study protocol, draft of patient information sheet and informed consent form
- Information of contact partners (study coordinators, CRO, …)
- Information on the status of agreements with Central Data Management

The above-mentioned information will be used to gain an impression of the study, followed by a telephone call where detailed agreements on

- scope of service

- content and format of patient information sheet and informed consent form
- targeted period, submission to ethics committee(s)

will be struck.

For information, please contact

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