# EVALUATION OF RESEARCH PROJECTS

## I. Objective

The objective of this Standard Operating Procedure (SOP) is to establish the documentation to be submitted and the administrative procedure to be followed for the evaluation of biomedical research projects in human beings and the subsequent notification of the resolution adopted.

## II. Scope of application

This procedure affects the personnel who carry out or intervene in the administrative processing of the research projects submitted to the Research Ethics Committee (CEI) of the University of Navarra.
Studies with medicines and medical devices not pertaining to this CEI are excluded.

## III. Responsibilities

- It is the responsibility of the main researcher to submit the complete documentation required by the CEI.
- It is the responsibility of the administrative staff in support of the CEI to verify the adequacy of the documentation submitted by the main researcher of the project (or person representing him/her) to the requirements of the CEI in the corresponding SOP.
- It is especially the responsibility of the technical secretary of the CEI to ensure that all projects meet the necessary requirements before they are distributed and evaluated by the CEI, as well as to notify the interested parties of the results of said evaluation within the established deadline.

## IV. Definitions

"Biomedical research projects in human beings" means those basic or applied research projects that require the participation of people (healthy or sick) as subjects of the research or that involve the use of biological samples of human origin or require the use of clinical data.

This procedure also affects the evaluation of applications for obtaining and storing biological samples of human origin for research purposes.

This SOP also deals with the following aspects:

- Acceptance of documentation for the evaluation of a project by the CEI
- Distribution of documentation to the different members of the CEI
- Definition of rapporteur and substitute for a study
- Evaluation of projects
- Notification of the resolution adopted in any of the sessions

## V. Documentation for evaluation

- The researcher and/or promoter requesting the evaluation by the CEI of a research project must submit the complete documentation in a manner that allows for a responsible declaration from the CEI.
- The documentation must in all cases be accompanied by the researcher's evaluation request and commitment sheet (Annex 1) as a presentation of the project, signed and sent by the main researcher.

- The necessary **documentation** for the evaluation of the project includes:
  - ***Final Project Protocol***
    The CEI must evaluate both the methodological and ethical aspects of the project, which must be open in order to include the considerations that the CEI may make to the researcher.
    The protocol must include:
    - *Justification of the study*: goals of the study and the background that justifies it.
      The participation of especially vulnerable populations (minors, disabled people) or the use of the placebo if any, should be explained in a reasoned manner.
    - *Patients:* selection criteria, incentives, recruitment method.
    - *Methodology:* study design, justification of the sample size.
    - If the study uses *biological samples:* It should be stated how they were collected or will be collected, if they will be kept for future studies, etc.
    - It should be noted down if the patient's *medical history* is to be accessed

  - ***Informed consent***
    The informed consent documentation consists of two elements:
    - ***Subject information sheet*** (healthy volunteer, patient or legal guardian).
      In language understandable for the subject, it must explain its research purposes and the most relevant aspects of the project and his/her participation.
    - ***Sheet(s) for signing of consent***
      These are specific forms for each study and each person who participates.

    In the case of an additional genetic study, specific consent may be necessary.

    If the storage of biological samples is considered, the manner in which it will be carried out must be specified and the provisions of Act 14/2007 of Biomedical Research and RD 1716/2011 must be taken into consideration.

    Biological samples may only be stored after the end of the study in the Biobank of the University of Navarra.

    The CEI has developed an informed consent model that, when adapted to its project, facilitates the task of researchers (Annex 2).

  - ***Certificate of the existence of insurance (if the study requires it)***

- ***In research involving invasive procedures in humans and obtaining of biological samples***

  It should be clear who will be responsible for the recruitment of the subjects, how the volunteers will be accessed, on whom access to medical history data will depend and who will be responsible for the custody and manipulation of the biological samples. Likewise, the destination of the samples once the project is finished must be defined.

- ***Economic report on the project***

  Indicate how the project will be financed and provide a detailed budget plan for its implementation. The budget must include all the tests and actions that, being necessary for the completion of the investigation, are not part of the patient's usual care process.

  When funding falls to the research team itself, it is essential to explain the existence of a special interest in the project.

- ***CEI evaluation request and researcher commitment sheet***

- Only those projects that present **all** the minimum documentation specified in this procedure will be evaluated. In the event that the documentation is incomplete, the CEI secretary will ask the main researcher for the necessary documentation. A project registration number will not be given until all documentation, including the evaluation request sheet, is complete.
- In order to receive the report of the University's CEI, the researcher must send the project to the Committee prior to sending the project to other external evaluation bodies (Announcements for scholarships and research grants, etc.).
- The request for evaluation and project documentation will be sent to the CEI Secretariat (*CEIC@unav.es*) with sufficient time for its evaluation in accordance with the deadlines established in the SOPs of the CEI.

## VI. Other considerations

The CEI will remind those main researchers conducting studies with minors that they must inform the Public Prosecutor of such.

The CEI will inform those researchers conducting observational studies with medicines that they must be sent to the Spanish Agency of Medicines and Medical Devices (AEMPS) for classification.

## VII. Deadline for admission of documentation

In general and in order to guarantee the quality of the evaluations carried out, those studies and/or research projects received in the CEI Secretariat will be evaluated up to **five (5) calendar days** before the CEI plenary meeting, provided that they meet the requirements set out in these regulations.

The documentation of the matters included in the Permanent meetings must be received at the CEI Secretariat at least 24 hours before the meeting.

## VIII. Documentation registration

Applications for evaluation of research projects will be received at the CEI Secretariat, where they will be registered and assigned a registration number. This number should be used as a reference in any communication between researchers and the CEI.

The evaluation request must be accompanied by the complete documentation in a manner that allows for the responsible declaration of the CEI.

The CEI administrative secretary will check the documentation presented with each application and determine if it meets the requirements laid out in point V of this procedure. If the documentation presented is incomplete, the researcher will be notified so that, in the shortest possible time, he/she can complete it. The request will remain pending in the meantime and the project cannot be evaluated.

Those projects whose documentation has been considered complete may be included in the agenda of the CEI session where they will be evaluated.

Prior to its inclusion in the agenda of a session, the CEI technical secretary shall designate, by delegation of the president, a rapporteur and a substitute for each project to be evaluated.

The rapporteur (and substitute, where appropriate) is the member of the CEI who will present and report the study in the evaluation session. He/she may communicate closely with the researcher to clarify any doubts that may arise prior to the evaluation. If he/she does not do so, the technical secretary will contact the researchers.

All members of the CEI will be potential rapporteurs and substitutes for the evaluation of a project in accordance with their competence and professional qualification, even if it can only address partial aspects of the study. Those members of the CEI that may have a conflict of interest with the submitted project will be excluded from the designation.

The designation will preferably be made depending on the type of study and/or type of illness to which the study is directed and on the basis of their respective training and qualification. A balanced distribution of the designations will be made among the different members of the CEI.

Where appropriate, the CEI will access the report of experts outside the Committee.

## IX. Documentation distribution

The secretary shall send to all members of the CEI the call for meetings at least **four (4) days in advance** (Friday prior to the meeting). The notice of the call will include the *Agenda* for the session and will be accompanied by the necessary documentation for study of the topics.

Only projects whose documentation has been considered sufficient and for which rapporteurs have been appointed may be included in the *Agenda* .

Ordinarily, the call and the attached documentation will be sent by email. If the documentation of a matter is complex or related to sensitive matters, the place and time in which the members of the CEI may consult it shall be indicated in the call notice.

## X. Evaluation process of research projects

The evaluation of the research projects will be conducted in the plenary (or extraordinary sessions convened for this purpose) of the CEI, after including the topics in the *Agenda* of the call.

For the evaluation, the rapporteur will present the project in summary form and will issue an interim report to which the opinions of the rest of the members of the CEI will be added (face-to-face or in writing), establishing a debate prior to the issuance of an expert opinion.

CEI members who cannot attend the session will be urged to submit their comments in writing.

Matters on which no agreement has been reached in the course of the deliberation will be put to the vote. The president will offer, in each case, the formula of the proposal to be voted on. A simple majority of valid votes is required for the approval of the proposals. In case of a tie, the president will have the casting vote.

The absence of the rapporteur and substitute for a project included in the *Agenda* will not prevent the evaluation of the project by the CEI, since all its members know and have been able to study the documentation of each project in advance and participate in a collegial way in the evaluation.

If any of the members of the CEI presents a conflict of interest in any project, he/she will leave the deliberations.

## XI. Issuance of the expert opinion. Notification of agreements

The result of the evaluation by the CEI of the research projects included in the Agenda of a session will be expressed in the minutes by means of an expert opinion.

The expert opinion will be the result of the assessment of the methodological, ethical and legal aspects of the project presented.

The expert opinion pertaining to the evaluation of a research project may have the following outcomes:

– **Approval:** when the evaluation of the project reveals that it is compliant in all aspects.

– **Denial:** when the evaluation of the project reveals that there are non-compliant aspects for which a substantial modification of the project itself is required.

Before reaching these expert opinions, the researcher may be asked to provide:

- **Minor clarifications:** when the evaluation reveals that it is convenient to ask the researcher or promoter for non-relevant clarifications. The answer to the clarifications could be evaluated in a Permanent session and, if this is satisfactory, approval of the project may be given. This approval must be communicated and endorsed at the next plenary session.

- **Major clarifications:** when the evaluation reveals that it is convenient to ask the researcher or promoter for relevant clarifications. The answer to the clarifications must be evaluated in a plenary session.

Within **five (5) working days** from the issuance of the expert opinion, the technical secretary shall notify the researcher in writing of the result thereof. Notification by other means is for informational purposes only and is not valid.

If the expert opinion requires a request for clarification, this must be clearly stated in the notification. The response of the researcher and/or promoter must make reference to this and must be expressed in writing. When the modifications affect the drafting of the report, they must be included and highlighted in the new version sent to the CEI.

In the event that the evaluation is negative (rejected), the reasons that have substantiated said decision shall be recorded in the notification.

In the event that a response from the main researcher is not received in the six months following the request for clarifications, a reminder will be sent and if no response is received, the project will be archived.

## XII. Certifications

**For the projects approved** in the minutes of each session, the technical secretary of the CEI will issue a certification stating the scientific validity of the project, and that it adheres to the legal regulations in force and satisfies the requirements demanded by biomedical research ethics.

For this purpose, he/she will issue a certificate where at least the following data will appear:

- Registration number of the project in the CEI
- Project title
- Main researcher
- Date of the CEI session in which it was approved
- Session type
- Certificate issuance date
- Signature of the CEI technical secretary

The certificate will be sent by email from the CEI Secretariat to the researcher within a maximum period of 48 hours from its approval.

## XIII. Storage and confidentiality of documentation

The technical secretary will keep an archive of the minutes corresponding to the CEI meetings and the certifications issued, and the correspondence between the two sets of documents may be checked at all times.

All documentation used for the evaluation of each project will be kept archived in the directory of the CEI, located on a secure server, which is backed up once a day.

In order to preserve the confidentiality of the documents, the members of the CEI undertake to keep the confidentiality of the issues discussed and documents used.

## XIV. Review of this SOP

The content of this procedure will be reviewed every two years, in the month of September of the even years. Occasional modifications may also be proposed when requested by half plus one of the members of the CEI in writing or when the president proposes such as a result of changes in the legislation that must be introduced in the procedure.