



FOLLOW-UP OF RESEARCH PROJECTS

I. OBJECTIVE

The purpose of this SOP is to establish the procedure for monitoring the research projects that have obtained a positive report from the CEI-UNAV.

II. SCOPE OF ACTION

This SOP will be applied to all research projects approved by the CEI-UNAV, whatever the Center of affiliation of their main researcher. The follow-up will be carried out from the beginning of the project until the reception of the final report or notification of its suspension.

III. RESPONSIBILITIES

The research project's main researcher has the obligation to inform the CEI-UNAV of:

- The resolution (approval or rejection) of the entity of which research assistance has been requested, if applicable.
- The beginning of the study.
- The annual project status sheet, which will be requested from the CEI-UNAV Secretariat.
- A summary of the final report that includes an assessment of the results obtained.
- Reference of the publications resulting from the project.

As a main obligation, and in a complementary manner to the annual monitoring of the CEI, the researcher undertakes to notify the CEI of any information relevant to the safety of the participating subjects.

The CEI will be obliged to

- Assess any amendment or modification of a protocol and issue a report in relevant cases.
- Evaluate the reports submitted by the researchers.
- Notify the researcher sufficiently in advance of on-site monitoring to be performed.
- Issue a monitoring report on site after its completion.
- Draw conclusions to improve the quality of research, by preparing annual monitoring reports.
- Prepare a report related to the follow-up of the projects and send it to the CUN Directorate or to the Vice-Rectorate for Research, as appropriate.

The UNAV Research Management Service will periodically send a report to the CEI Secretariat, notifying the projects that have been approved in the various announcements. The CEI will try to ascertain the status of the projects from the person responsible for the ICT.

The certificate of approval of a project will include an obligation to notify the CEI of the resolution of the announcement for which the project is submitted (when appropriate), as well as to complete the final follow-up form. It will also include the possibility of requesting a review of the project throughout its development, as well as the special



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obligation to notify the CEI of any information relevant to the safety of the participating subjects.

IV. BASIC FOLLOW-UP PROCEDURE

The CEI Secretariat shall request from researchers, in writing, the annual reports of the approved studies.

In the month of January of each year, the CEI Secretariat will issue the file of Annex 1 in a nominal manner for each project approved in the expired calendar year. It will prepare a document for each project, which will include the data that appears in the CEI (title, researcher, center). Likewise, this document will be issued for those projects approved in previous years, from which the “end of project” notification has not yet been received.

The submission of the annual reports by the researcher must be made prior to the date included in the file as “deadline for delivery”.

The researcher should send the reports to the CEI, preferably by email (ceic@unav.es).

If, after the established deadlines, no response has been received, a letter will be sent to the researcher, reminding him/her of his/her obligation to inform the CEI within the planned period, in order to be able to prepare the annual CEI follow-up report, and for it to be sent to and filed in the Vice-Rectorate for Research.

If no response has been received after one month, the CEI may establish the measures it deems appropriate to ensure compliance with this requirement.

Each year, the CEI Secretariat will prepare the annual report on the follow up of research projects.

V. OTHER PROCEDURES

The CEI may decide to carry out an on-site follow-up of an approved research project.

To do this, it must send a notification to the main researcher, at least 15 days before the follow-up. The calendar of the follow-up visit will be agreed with the researcher.

In the notification to the researcher, the aspects of the follow-up will be indicated, which will be evaluated, and which may include some or all of the following points:

- Protocol used in the realization of the project
- Information sheet offered to participants
- Informed consent from the included participants
- Status of the samples: identification, conservation, custody, anonymization procedures.
- Responsibilities of the members of the research team, custody of clinical data.

After this face-to-face follow-up, a report will be issued, which will be sent to the researcher and to the Management of his/her work center. This aspect will be communicated to the researcher before carrying out the follow-up, and the researcher may review the report before it is sent to the Management, and will have the right to clarify the points with which he/she is not satisfied. It is up to the CEI to ultimately decide the final version of the report that will be sent to the Management of the work center.