Procedures

1. Regular Review Procedure

To encourage non-biomedical research projects conducted at UPF to fulfill basic ethics and personal data protection requirements, CIREP has established the ethics and personal data protection review procedure described below.

1.1. Review Application Reception

CIREP receives a complete application, which contains the following documents.

1.1.1. *Self-Assessment Ethics Checklist - Mandatory*

The ethics and personal data protection checklist helps the principal investigator (PI) determine whether a project must be submitted for review and the accompanying information and documentation that needs to be provided (including whether the PI needs to complete the data protection impact assessment [DPIA] form; see 1.1.3).

1.1.2. *Protocol Form - Mandatory*

In the protocol form one must describe the research objectives, methodology, participants, recruitment methods, personal data processing strategies, and other ethical aspects of the project.

1.1.3. *DPIA Form - If Applicable*

Exceptionally (if applicable based on the responses to the checklist), the DPIA form will have to be filled out.

1.1.4. *Informed Consent Documentation - If Applicable*

The informed consent documentation must describe the participation in a clear and intelligible manner so that potential participants can make an informed decision whether to participate or not.

1.1.5. *Additional Supporting Documentation* - If Applicable

The application must include any other document detailing relevant information for the ethics review, such as a risk management plan for projects with fieldwork in risk areas, interview scripts or questionnaires (even if in a preliminary form), non-disclosure agreement if personal data is to be shared with external researchers, etc.

1.2. Prescreening

Before registering the new application, CIREP verifies that the PI has completed the online training on research ethics and personal data protection and that all the documentation provided is complete and the information included is sufficient to evaluate the project. In the prescreening phase, PIs may be required to provide additional information. If the PI has not completed the online training, they will be asked to do so before their application is processed.

1.3. Ethics Review

After the application has been checked and registered, it is sent to the Committee members, a coordinator is assigned, and the review process, which includes different steps, is formally initiated.

1.3.1. *External Peer Review*

Apart from the evaluation by a CIREP member, another independent peer review is requested from an expert in the relevant field. The external peer reviewer examines all the documentation and fills out the external peer review form.

1.3.2. *Personal Data Protection Review*

If the project involves processing personal data, a Data Protection expert reviews its adequacy to the relevant regulations and provides an independent assessment.

1.3.3. *Integrated Review*

The coordinator combines the different reports with their own into an integrated review draft that includes recommendations and requirements that the PI needs to address to improve their application. The draft is shared with all the Committee members.

1.3.4. *Discussion*

CIREP members meet on a monthly basis to evaluate the applications. As a consequence, a decision on the ethics and personal data review is reached, and a final version of the integrated review is produced.

1.3.5. *Adaptations - If Applicable*

The integrated review is sent to the PI, who has to revise and resubmit their original application within two weeks.

1.3.6. *Final Decision*

The Committee evaluates the revised documentation. At this point, most applications are approved, although some applications may require further revisions.

1.4. Approval

An ethics compliance certificate is issued. In addition, for UPF projects that involve personal data processing, a personal data certificate is also expedited by UPF's Data Protection officer.

1.5. Remarks

- CIREP does not review research projects retroactively. Thus, researchers need to apply for ethics review and obtain the approval **before** they start their project.
- The meeting calendar and tentative application submission deadlines are listed here. The estimated duration of the ethics and data protection review procedure for new applications is 12 weeks. An expedited procedure may be available for applications following the approved protocol for the Behavioral Experimental Sciences Laboratory (BESLab), minor modifications of protocols previously approved by CIREP, validation of protocols approved by other research ethics committees, and funded projects with a duration under 12 months.
- Modifications to approved protocols must be reported to CIREP, which may lead to a new review. If you need to introduce changes to a protocol approved by CIREP, please notify the Committee at secretaria.cirep@upf.edu and resubmit the approved documents with the changes you would like to introduce clearly marked. You should notify your intention to introduce changes before you actually implement them.

2. Other Review Procedures

Review procedures that depart from the regular review procedure are described below. For each procedure, the cases in which it can be applied are listed and the differences between that procedure and the regular one are indicated.

2.1. Expedited Review Procedure

The expedited review procedure was adopted to allow for a prompt response to urgent projects related to the COVID-19 pandemic. This procedure can be applied in the following cases:

- projects that follow the BESLab protocol, approved by CIREP,
- minor modifications of protocols already approved by CIREP,
- validation of protocols approved by other research ethics committees,
- funded projects with a duration under 12 months,

- other exceptional cases that require urgent review.

Unlike in the regular procedure and with the aim of reducing the response time, the expedited review procedure waives the need for an external review. In addition, the integrated review is discussed via email instead of at a Committee meeting. The Committee members can share their comments for 48 hours, after which a final version of the integrated review is produced. The average duration of an expedited procedure is 6 weeks.

2.1.1. *BESLab Projects Review Procedure*

On 3 July 2020 CIREP approved a general protocol (ref. 145) for BESLab experiments. The protocol includes detailed information and specific application forms. For projects that intend to collect data through the BESLab, PIs must use these adapted application forms and check the relevant options. In addition, PIs must detail any proposed departures from the approved protocol, if any.

Projects that followed the BESLab protocol are reviewed in an expedited fashion: the procedure dispenses with the external review as well as the data protection review unless the coordinator requires them.

2.2. Validation Procedure

When a project has been reviewed and approved by another research ethics committee, CIREP can issue a validation certificate if necessary. Validation applications are assigned to the Committee's vice-chair and to the Data Protection officer. They review the project and determine whether it can be validated. If applicable, a validation certificate is issued. The average duration of the validation procedure is 3 weeks.

Validation applications include the following documents.

2.2.1. *Validation Form - Mandatory*

In the validation form one must describe the project and introduce information about the research team members and the committee that has reviewed the project.

2.2.2. *Protocol Form - If Applicable*

If the UPF research team is involved in personal data processing, the PI must fill out section 5 (on personal data protection) in the protocol form.

2.2.3. *Ethics Compliance Certificate - Mandatory*

The ethics compliance certificate issued by the committee that has reviewed the project must be attached.

2.2.4. *Approved Protocol - Mandatory*

The documentation reviewed by the committee must be attached as well.

2.2.5. *Informed Consent Documentation - If Applicable*

The informed consent documentation must describe the participation in a clear and intelligible manner so that potential participants can make an informed decision whether to participate or not.

2.3. Modification Handling and Review Procedure

Modifications to approved protocols must be reported to CIREP, as they may require a new review. If you need to introduce changes to a protocol approved by CIREP, please notify the Committee at secretaria.cirep@upf.edu and resubmit the approved documents with the changes clearly marked. The changes in the protocol cannot be implemented until CIREP concludes the new review.

The application must only include the documents that the IP would like to modify. After the new application has been checked and registered, it is assigned to the same coordinator and Data Protection reviewer who reviewed the original application. The type and extent of the changes determine the way the modification is handled. If the changes are minor and have no ethical or personal data protection implications, the Committee registers the changes and notifies the PI that they can proceed with the modifications. Alternatively, if the changes are substantial, the project is reviewed again (following the regular or expedited review procedure as necessary). The duration of the modification handling procedure is very variable depending on whether a new review is necessary or not and the review procedure.