

Research protocol

Research ethics resources kit

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**Universitat Oberta
de Catalunya**

Research protocol

Before undertaking a research project, it is first necessary to draw up a research protocol which specifies the study's features and which it must comply with in its performance. This document establishes the study's rationale, objectives, design, methodology and planned analyses of the results, and also the conditions under which it will be carried out. In addition, this document must guarantee that sufficient information is available to assess the project.

The main requirements that the UOC's Research Protocol must take into account are given below, adapting them as necessary to different types of research. Formalization of the Research Protocol must be sent to the [UOC's Ethics Board](#) when this is requested by the funding organization, and also when the participants in the experiments are people exposed to some type of risk, minors or in a situation that makes them vulnerable. If there is any doubt, the issue or the possible protocol can also be referred to the Board.

The protocol that will be provided to the Board can be the [Form for evaluation by the UOC's Ethics Board](#), or a document in the format that the project's funding organization recommends using.

Although the protocol may have varying degrees of exhaustiveness, the effort to systematize may be beneficial in adequately focusing the research project and may also facilitate subsequent publication of the results. We should not forget that disseminating results is an ethical imperative for researchers and an indicator of the quality and rigour with which the research has been carried out.

Main regulatory requirements in scientific praxis (protocols):

- Definition of the protocol

Those scientific activities that require it must be based on a written protocol. At the UOC, this protocol addresses research projects that involve experimentation with humans.

The protocol is defined as a document that describes, in detail, the activity that will be carried out. If the research activity directly involves people, the protocol must specify the planned activities, in accordance with the University's Code of Good Practice. This [protocol](#) must be examined and validated by the UOC's Research Ethics Board.

- Content of the protocol

The protocol will include, at least, the proposal's background, the specific objectives, the methodology that will be used, the work programme and the schedule, the resources that are available and necessary, the research team, the research participants, risk control, participant information and compensation, and the security of the data that are collected.

Because of the nature of the research most commonly performed at the University, the form places particular emphasis on the aspects related with personal data. Thus, information is requested about the data collection methods (the sources, the processes for obtaining data, whether they are part of the research or come from data that was collected earlier, etc.), aspects related with the participants' consent to the research and preserving the participants' personal identity.

- Expansion or modification of the protocol

If the research activity is expanded or modified, the appropriate complementary protocol will be written.

- Nomenclature of the documentation

In order to ensure adequate documentation traceability, the protocols must be identified with a version and a date, so that a record is kept of the successive modifications and versions submitted to the UOC's Research Ethics Board.

- Responsibilities of the University

By law, university and research centres must guarantee that the infrastructures comply with regulatory and security requirements and the appropriate authorizations have been given in the case of the specific practices that require them.

- Use of third-party facilities and equipment

Research activities that involve the use of third-party facilities and equipment must have their protocol approved beforehand by the manager of the institution that owns the equipment.

- Collaborative projects

When a research activity entails cooperation between two groups in the same organization or different organizations, the scope and duration of the cooperation, and the procedure for preparing and validating the research protocol must be defined in writing.

- Confidentiality of the protocol

The content of the protocol will not be confidential except when it may be agreed to restrict distribution of certain protocols or parts thereof for competitiveness reasons or the existence of prior agreements signed with external partners. In any case, the protocol will be accessible for assessment by the members of the UOC's Research Ethics Board and, upon request, by the members of the UOC's Governing Council, the UOC's Legal Office, and the FUOC's Board of Trustees.

Protocol form to be submitted to the UOC's Ethics Board:

Alternative form for students, affiliated teaching staff and researchers from other institutions: