



EDCTP

European & Developing Countries
Clinical Trials Partnership

Frequently asked questions (FAQs) Ethics and Regulatory Capacities

Disclaimer: The FAQs are for information only and do not constitute a legally binding document. The legal basis for information in the FAQs can be found in the Horizon 2020 Rules for Participation and the EDCTP Annual Work Plans

For more information, please go to the EDCTP website: www.edctp.org



Purpose of the FAQs

These FAQs provide guidance for applicants to the EDCTP2 Call for Proposals “Ethics and Regulatory Capacities” to supplement the information provided in the Call text and Call documents. The FAQs will be updated regularly in response to questions received from applicants to the call. Please also refer to the [EDCTP2 FAQs](#).

Rules for participation and funding

Q: Country [X] does not have a National Ethics Committee. Can my Institutional Review Board/Institutional Ethics Committee participate in our application instead?

A: Institutional Review Boards and Research Ethics Committees applying without the involvement of the legal entity (ies) hosting a National Ethics Committee (NEC) and/or National Regulatory Authority (NRA) are not eligible. Applications must include at least one legal entity hosting a NEC and/or NRA in a sub-Saharan African country. The legal entity that hosts the NEC and/or NRA must be a Participant in the application.

Q: I am the chairman of the National Ethics Committee. Can I apply for funding for the ethics committee that I chair?

A: Individuals submit applications to EDCTP on behalf of the legal entity (organisation) that they represent. For this call, the legal entity that hosts the National Ethics Committee must be a participant in the application. The ethics committee is not a legal entity in its own right and therefore the application should be submitted by the legal entity that hosts the National Ethics Committee.

Q: Can multiple applications be submitted to the call to support the same National Ethics Committee or National Regulatory Authority?

Although there is nothing to prevent submission of multiple proposals, this is discouraged. Please bear in mind that each proposal must be a stand-alone proposal (interdependent projects cannot be divided into separate proposals). If proposals look similar, then applicants may be asked to withdraw one or more proposals. EDCTP expects coordination at the national level via the legal entities that host the National Ethics Committee and/or National Regulatory Authority and discourages multiple applications to support the same ethics committee and/or regulatory authority.

Q: The regulatory authority on whose behalf I am applying received funding from EDCTP2 last year. Can I apply for more funding to add new activities to the project?

A: Under current EDCTP2 rules, there is no restriction on submitting proposals for funding for national ethics committees and national regulatory authorities that have already been supported. However, such repeat applications may be considered to have lower impact on evaluation.

Q: How do I add the National Ethics Committee and National Regulatory Authority as co-applicants?

A: The legal entity that hosts the National Ethics Committee (NEC) and/or National Regulatory Authority (NRA) must either be the Coordinator or be added as a Participant(s) in the application. You must identify an individual(s), employed at the legal entity (-ies) hosting the NEC and/or NRA, who agrees to participate in the application. He/she will receive an email asking to confirm their participation (on behalf of the legal entity) in the application. It is not sufficient to discuss the NEC and NRA in the application and simply to state that they are involved – the legal entities hosting the NEC and/or NRA must be added as Participants and confirm their participation.