



# EDCTP Guidelines on Ethics

## ***Ethical considerations***

Regulatory authorities require that all new investigational medicinal products intended for use in humans must be shown to be safe, effective and of the highest quality.

All studies that are funded by EDCTP must be implemented in accordance with the standards and codes of conduct accepted by the **International Conference on Harmonisation (ICH)** guidelines (follow the link on the links page of our website [www.edctp.org](http://www.edctp.org)) and in compliance with the local ethics requirements of the countries where these studies are to be conducted.

In accordance with these guidelines, all clinical studies have to be submitted to and approved by an **independent Ethics Committee** that complies with the World Health Organisation Operational Guidelines for Ethics Committees That Review Biomedical Research (TDR/PRD/ETHICS/2000.1). A link to this document can be found at the links page of our website ([www.edctp.org](http://www.edctp.org)) together with the complementary guidelines to Operational Guidelines for Ethics Committees That Review Biomedical Research: Surveying and Evaluating Ethical Review Practices (TDR/PRD/ETHICS/2002.1).

"Compliance with these guidelines helps to ensure that rights, safety and well-being of research participants are promoted and that the results of the investigations are credible". The role of the Ethics Committee is to safeguard the interest of volunteers taking part in studies.

***EDCTP will not support any studies that have not obtained approval from the local Ethics Committee.***

Applicants are therefore encouraged to pay due attention to the various ethical aspects in the planning of studies including the process of obtaining verbal/ written **informed consent**, the obligations of investigators and **sponsors**, benefits and risks of study participation, recruitment, cultural values, and confidentiality measures in accordance to the **World Medical Association Declaration of Helsinki** ethical principles for medical research involving human subjects (follow the link on the links page of our website [www.edctp.org](http://www.edctp.org)). You will be asked to identify potential ethical issues in the application form (questions 2.12 and 2.13).

## ***Regulatory requirements for conducting clinical trials***

**Regulatory requirements** are part of the process of drug discovery and drug development and describe what is necessary for a new medicinal product to be approved for marketing in any country. Prior to testing on humans in clinical trials, medicinal products must be subjected to rigorous testing in the laboratory (preclinical trials) for which animals are used and must be approved by a competent authority for use in humans.

Although EDCTP's mandate focuses on phase II and III clinical trials, all investigational products used in EDCTP supported trials must have sufficient efficacy



and safety data available from preclinical and phase I evaluation studies and must have been approved by a competent body. This is in order to ensure safety and enable future registration of these products in compliance with the [International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use \(ICH\)](#).

It is important that the rights, safety and well being of volunteers participating in clinical trials of new medicines are observed in sub-Saharan Africa. Although regulatory capacities in different countries may differ, all EDCTP supported studies must comply with the international ethical and scientific standards (**GCP - Good Clinical Practice**).

*In countries where approval of clinical trials from the **National Regulatory Authorities (NRAs)** is a prerequisite, EDCTP will require this clearance before funding these studies.*

The acting **sponsor** of the clinical trial components of the EDCTP application needs to be an identified legal entity with documented experience to act as a sponsor. Clear guidance is also available from the **World Medical Association's Declaration of Helsinki** (follow the link on the links page of our website [www.edctp.org](http://www.edctp.org)), the MRC Guidelines for **Good Clinical Practice** in Clinical Trials (to be downloaded from our website [www.edctp.org](http://www.edctp.org)) and the EU Directive 2001/20/**EC** on Good Clinical Practice (to be downloaded from our website [www.edctp.org](http://www.edctp.org)).