Expectations for standards of research conduct involving human participants

All Cambridge-Africa ALBORADA Research Fund projects **must** consider the ethical aspects of the research and, where applicable, have all the necessary ethical and regulatory approvals in place prior to commencement of the research. It is up to the PIs to ensure that appropriate ethical review is obtained. Since the Cambridge-Africa ALBORADA Research Fund awards are for research to be undertaken in Africa ethical approval will need to be sought by the African research lead with the relevant authorities in the African country/countries where the research is being undertaken. Ethical approval is also required from the relevant University of Cambridge research ethics committee. In addition, all projects involving human participants will require insurance. We signpost Cambridge PIs to Rose Eichenberger, Global Health Research Manager at the Research Operations Office (re305@cam.ac.uk) and Jane Gaffa, Research Governance Adviser - International Studies at the clinical school (jg788@medschl.cam.ac.uk).

It is a requirement that the Cambridge PI keeps a study file including copies of the ethics documentation and approval notifications as well as, where there are human research participants, exemplar consent and participant information forms. These should be available in English as well as local languages used in the study. Retrospective ethical reviews are not permitted. Researchers need to comply with the Nagoya Protocol which concerns research involving non-human genetic material of plant, animal, microbial or other origin. Researchers must consider and maintain high standards in relation to safeguarding.

There are some principles underlying ethical research that you will be expected to have addressed:

1. Research must be truly collaborative in its design, ownership and authorship/publication of findings.
2. Respecting autonomy - this includes providing research participants with sufficient information to make informed decisions on whether to participate i.e. informed consent and providing information on and means of withdrawing consent.
3. Ensuring confidentiality. This is vital for all research. Particular consideration should be given to research on diseases carrying stigma to prevent stigmatisation of participants in field-based research.
4. Undertaking a thorough risk assessment and harm avoidance plan for harms that could arise from the research. Any potential harms should be proportionate to the benefits and will need careful consideration by ethical review processes. The research should ensure that the benefits outweigh any harms and that the research is designed to maximise the chance of obtaining useful results.
5. Research involving individuals under the age of 18, vulnerable groups and those lacking the capacity to consent require specific protection. Research with those who have experienced trauma (for example gender-based violence and child soldiers) must not be retraumatised by the research.
6. Putting in place means of disseminating the results both to the communities involved in the research including the research participants and to policy makers.
7. Any potential or actual conflicts of interest must be declared.

Further guidance and policies

University of Cambridge guidance

Applying for ethical approval: Basic Principles

International Studies carried out by University Employees

Ethical Review of Overseas Research

University of Cambridge Policy on Ethics of Research Involving Human Participants & Personal Data

UK and International guidance

UK Clinical Ethics Network

Guidance on Safeguarding in International Development Research UK CDR

International Ethical Guidelines for Health-related Research Involving Humans (produced by CIOMS)

https://www.research-operations.admin.cam.ac.uk/nagoya-protocol.