



Guidance for Submitting Applications for Ethical Review of Research Protocols

The purpose of this summary is to ensure that all proposal protocols conform to:

- (i) Generally Accepted Scientific Principles
- (ii) The Nigerian National Code for Health Research Ethics (www.nhrec.net)

In order to submit a protocol to the Ethics Committee, you will find the information in this guide useful. For ethical review of protocol, the Committee needs the following materials

1. 4 paper copies of research protocol and an electronic version (in MSWord or pdf format). The protocol should have the following sections
 - Cover page that shows the following
 - Title of research, Full Names and Qualifications of investigators, Sponsors (where applicable), Other Collaborating Institutions and Investigators,
 - Corresponding Investigator, who must be the Project Principal Investigator (PI) or Local PI of the research and bears legal responsibility for the research.

The research proposal should contain enough information to allow the committee judge the ethical aspects of the research.

The protocol *may* contain the following sections:

- Background of Study - Describing current knowledge about the research.
- Rationale for the study
- Objectives of the study
- Research Methodology
 - Study design - stating clearly the nature of the study (descriptive, drug trial, experimental)
 - Sample size determination
 - Sampling strategy/Interview including inclusion/exclusion criteria/frequency of interviews
 - Statement on invasive sampling (blood, tissue etc) inclusion/exclusion criteria and frequency of sampling
 - Data collection procedure
 - Physical examination procedure if indicated
 - Follow up details if required
 - Laboratory procedure to be used
 - Intervention to be used
 - Data analysis method to be used

- Copies of Questionnaires, Survey instruments, Case report forms and Samples of Drug or other Devices to be used in the study must be included in the protocol
 - The protocol should contain an ethical considerations section as a separate entity. In this section, researcher is to clearly identify the potential ethical problems that may arise in the research and address these. For example, if conducting research on prisoner, the issue of vulnerability and diminished autonomy is important and the researcher should address this concern in the protocol
2. Principal Investigator's CV in NIH Biosketch format (maximum 2 pages, containing enough information to judge the ability of the PI to conduct the research)
 3. Supervisor's attestation statement. (Where applicable – in student's research, for example).
 4. Co-Investigators attestation statement. (Where applicable) or Copy of letter(s) of support from co-investigator(s), laboratories and sources of required resources (where the researcher indicates that (s)he will be collaborating with others.
 5. Sponsor's attestation statement i.e. letter of sponsorship. (Where applicable)
 6. Materials Transfer Agreement (MTA - Where samples will be shipped out of Nigeria – see prototype on the NHREC website for guidance)
 7. Clinical Trial Agreement (CTA – Where the research is being conducted on behalf of a sponsor) and any other agreement that may have been signed and is relevant to the participants in the research.
 8. One page plain language summary of the research including the title of the study, research design, methodology, principal exposure and outcome variables.
 9. **THE INFORMED CONSENT FORM ON INSTITUTIONAL OR DEPARTMENTAL LETTER HEADED PAPER. Please see NHREC prototype consent form to guide you in designing your own consent form.**

10. ATTENTION RESEARCHER:

When all prescribed application materials have been assembled, here are the steps to follow:

1. Write an application letter to the Chairperson, Ethics Committee
2. Complete an application form.
3. Compile all prescribed application materials and ensure that they are properly numbered and do not have many typographical errors.
4. Ensure that all relevant institutional officials have signed off on the protocol including a Supervisor in case of student's research.
5. Attach a copy of proof that you have recently undertaken satisfactory research ethics training within the last 2 years. Examples of such training include training programs conducted by your institution's ethics committee, online training programs such as CITI (see NHREC <http://www.nhrec.net> or West African Bioethics Training Program <http://www.westafricanbioethics.net> website for suitable online training programs). NHREC now requires if your certificate of training in research ethics is not one obtained from an NHREC approved workshop in Nigeria, that you present two certificates from the CITI or TRREE Initiative. **One certificate from the 'basic'**

modules for either biomedical investigators or social and behavioural investigators; and another certificate on the Nigerian National Code of Health Research Ethics

6. The following guide will help you obtain these ethics training certificates from the CITI program. Another guide on the TRREE initiative will be available soon and this guidance note will be updated accordingly:

PROCESS FOR ONLINE TRAINING IN RESEARCH ETHICS

Click this link to go to the training website to register and start your training: <http://www.citiprogram.org/>

Here you click on 'New User'. This will take you to a page where you are to respond to 7 queries. All are straightforward but consider these for the following queries.

- No 1. 'Participating Institution'. Here, from the drop-down list, select the option, 'West African Bioethics Training Program' and then ignore all the other lines under No 1 and simply go ahead to No 2. to create your unique username and password.
- No 6. Simply select the option 'No' here since the CME credits do not apply to institutions in Nigeria (unless if you are working for a US institution where it may apply).

When you are done with query No. 7, click and 'submit'. This will then take you to the next page where you are asked to provide more personal details. Please take care in putting your name as your certificate will be printed with this name.

The next step is for you to select your curriculum. Question 1 is a requirement for all investigators conducting studies in Nigeria, while in Question 2, you should select the learner group most appropriate to you. Based on these responses, the programme will select the modules you will be taking, and will take you to the page where you can start your training. You will see un-completed modules highlighted in red. Click on these red highlights to commence or continue a module. You can stop at anytime and comeback and continue from there.

For more information please download and read a copy of the Nigerian Code for Health Research Ethics at www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf. You can also contact NHREC via the following: deskofficer@nhrec.net, chairman@nhrec.net