



## **Stepwise Guide for Online Research Ethics Training Required for Ethical Review of Research in Nigeria**

According to the Nigeria National Code of Health Research Ethics, all investigators applying for ethics review of any proposed human or animal research must submit among other documents **“Evidence of NHREC certified informed consent training by applicant and co-investigator(s) undertaken within 2 years of the date of submission of a valid application to HREC” (NCHRE section K subsection f subpart 9).**

Submitting **ANY** of the following would fulfill this requirement:

**Section 1: For research that is not Clinical Trials.** Researchers planning to conduct research other than clinical trials should complete any of the following:

- a) Certificate from an NHREC approved face-to-face training course/program
- b) Relevant **CITI (Collaborative Institutional Training Initiative) online ethics training courses**
  - i. If the researcher is a **biomedical investigator**, then the researcher should do:  
Content Series: Human Research  
Learner Group/Course: Group 1 - Investigators  
Course-Stage: Basic Course
  - ii. If the researcher is a **social and behavioral science investigator**, then the researcher should do:  
Content Series: Human Research  
Learner Group/Course: Group 2 - Investigators  
Course-Stage: Basic Course
  - iii. If the researcher is a **biomedical student**, then the researcher should do:  
Content Series: Human Research  
Learner Group/Course: Group 4 - Students  
Course-Stage: Basic Course
  - iv. If the researcher is a **social and behavioral science student**, then the researcher should do:  
Content Series: Human Research  
Learner Group/Course: Group 5 - Students

In addition, in order to incorporate aspects of research ethics that are relevant to the Nigerian jurisdiction, the researcher should complete the module designed for this purpose:

Content Series: NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS

Learner Group/Course: NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS

Course-Stage: Stage 1

- c) Relevant TRREE (Training And Resources in Research Ethics Evaluation) online ethics training courses. For all categories of researchers, the following modules should be completed :
  - i. Module 1 – Introduction to research
  - ii. Module 3.1 – Informed consent
  - iii. The Nigeria module under the continents/countries category.

**Section 2: For Clinical Trials.** In addition to the basic training outlined in section 1.

Researchers planning to conduct clinical trials should also complete any of the following:

- a. Certificate from an NHREC approved face-to-face training course/program on Good Clinical Practice
- b. Relevant CITI (Collaborative Institutional Training Initiative) online ethics training courses
  - i. Good Clinical Practice
- c. Relevant TRREE online ethics course
  - i. Module 3.2 Good Clinical Practice

**Section 3: Optional Training Modules** for members of ethics committees are available on the CITI website and these include:

- a. Training for ethics committees members
  - Content Series: Human Research
  - Learner Group/Course: Group 3 – IRB Members
  - Course-Stage: Basic Course
- b. Training for ethics committees chairs

- c. General training for members, chairs and administrators of ethics committees

**Section 4:** If you are working on a U.S. Federal Government funded research project or grant, according to NOT-OD-10-019 of Nov. 24<sup>th</sup> 2009, you are required to undertake a course in **Responsible Conduct of Biomedical Research** which includes face-to-face training. The CITI (Collaborative Institutional Training Initiative) online ethics training program contains a course which you can do but this requires supplementary training in order to satisfy the need for face-to-face training.

**Note:** All required certificates must have been obtained less than two years from the date when the application was submitted for ethics review

Below are stepwise guides and algorithm for the CITI and TRREE ethics training courses. Investigators wishing to obtain required ethics training certificates for the purposes of submitting applications for ethics review to NHREC could choose from either the CITI or TRREE trainings to fulfill this requirement.

### 1. How to register for the CITI ethics trainings

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.

### Category of investigators and types of CITI trainings required

Category of  
researcher/investigator

CITI training modules required

Clinical Trials and quasi experimental studies

- Group 1 Investigators- basic course for biomedical investigators
- CITI Good Clinical Practice Course
- **NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS** – required for all investigators and students conducting research in Nigeria

other epidemiological or clinical/laboratory based studies

- Group 1 Investigators- basic course for biomedical investigators
- **NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS** – required for all investigators and students conducting research in Nigeria

social and behavioural/humanities studies/KAPB surveys/non clinical programme evaluations/marketing studies

- Group 2 Investigators- basic course for social and behavioral investigators
- **NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS** – required for all investigators and students conducting research in Nigeria

Biomedical Science Students

- Group 4 Investigators- basic course for biomedical investigators
- **NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS** – required for all investigators and students conducting research in Nigeria

Social and Behavioral Science/Humanities Students

- Group 5 Investigators- basic course for social and behavioral investigators
- **NIGERIAN NATIONAL CODE FOR HEALTH RESEARCH ETHICS** – required for all investigators and students conducting research in Nigeria

All Investigators funded by US Federal Agencies

- **Responsible Conduct of Biomedical Research** Course

### 3. How to register for the TRREE ethics trainings

- Click on <http://elearning.trree.org/> to go to the TRREE home page
- On the home page click the [create new account](#) link to create your own account
- Upon filling the new account form an email will be sent to your email address immediately
- Read your email, and click on the web link it contains.
- Your account will be confirmed and you will be logged in.
- Now, select the course you want to participate in.
- If you are prompted for an "enrolment key" - use the one that your teacher has given you. This will "enrol" you in the course.
- You can now access the full course. From now on you will only need to enter your personal username and password (in the form on this page) to log in and access any course you have enrolled in.

### 4. Category of investigators and types of TRREE trainings required

Category of researcher/investigator	TRREE training modules required
All researchers/professionals wishing to collect data from or about humans or animals	<ul style="list-style-type: none"><li>• Module 1.0 (Introduction)</li><li>• Module 2.1 (Research ethics evaluation)</li><li>• Module 3.1 (Informed consent)</li><li>• Nigerian National Ethics Code Supplement (located under the "National Supplements" section on the home page)</li></ul>
Investigators conducting clinical trials/quasi experimental studies	<ul style="list-style-type: none"><li>• Module 1.0 (Introduction)</li><li>• Module 2.1 (Research ethics evaluation)</li><li>• Module 3.1 (Informed consent)</li><li>• Module 3.2 (Good Clinical Practice)</li><li>• Nigerian National Ethics Code Supplement (located under the "National Supplements" section on the home page)</li></ul>
Investigators conducting clinical trials/quasi experiments of vaccines including HIV/AIDS vaccines	<ul style="list-style-type: none"><li>• Module 1.0 (Introduction)</li><li>• Module 2.1 (Research ethics evaluation)</li><li>• Module 3.1 (Informed consent)</li><li>• Module 3.2 (Good Clinical Practice)</li><li>• Module 3.3 (HIV vaccine trials)</li><li>• Nigerian National Ethics Code Supplement (located under the "National Supplements" section on the home page)</li></ul>

For more information please download and read a copy of the Nigerian Code for Health Research Ethics at [http://www.nhrec.net/nhrec/NCHRE\\_10.pdf](http://www.nhrec.net/nhrec/NCHRE_10.pdf). You can also contact NHREC via the following: [deskofficer@nhrec.net](mailto:deskofficer@nhrec.net), [chairman@nhrec.net](mailto:chairman@nhrec.net)