

ETHICS IN RESEARCH
University of Rwanda
College of Medicine and Health Sciences
School of Public Health

1. Contact information

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Time for contact: Any time during working hours, preferably on emails.

2. Course description

This course is designed to prepare the students to their future role of investigators who will be involved in the design and/or conduct of research involving human subjects to understand their obligations to protect the rights and welfare of subjects in research. This course introduces the basic concepts, principles, and issues related to the protection of research participants. The course will discuss the principles of ethics in research, the development of contemporary research ethics, and give an overview of the responsibilities of ethics committees and of researchers when conducting a research. Lectures are complemented by practical sessions devoted to case studies, exercises, or critique of current examples of public health studies.

3. Course objectives

Upon completion of this course, the students will be able to:

1. Understand the importance of study design in the protection of research participants
2. Apply the three fundamental principles of research ethics in the development, review, and conduct of research involving human participants

3. Describe the history and importance of human subjects protections
4. Describe additional protections needed for vulnerable populations
5. Understand additional issues that should be considered for international research
6. List and explain the essential elements of informed consent
7. Describe appropriate procedures for recruiting research participants and obtaining informed consent.
8. Describe the role, composition, and function of Research Ethics Committees

4. **Suggested readings**

- Teaching the Responsible Conduct of Research in Humans by UCLA
- Ethics and Research in the Community by Bryn Mawr College and the Massachusetts College of Pharmacy and Health Sciences
- Human Participant Protections Education for Research Teams by National Cancer Institute
- Entering a Clinical Trial: Is it right for you by Dana-Farber Cancer Institute - <http://www.fhi.org/training/fr/Retc/>
- The Nuffield Council on Bioethics: <http://www.nuffieldbioethics.org/>

5. **Student responsibilities and grading**

- Students are required to attend class.
- Students are required to turn in all in-class assignments on time.
- Students are required to write a research proposal including a consent form in a Word document and provide the instructor with an electronic copy of their proposal two weeks after the last day of class. 10% Attendance and class participation 40% Assignments:
 - o 10% Attendance and class participation
 - o 40% Assignments: (individual) NIH course on “Protecting Human Research Participants (<http://phrp.nihtraining.com/users/login.php>)
 - o 20% PAPER/Case studies discussion
 - o 30% Written exam

6. **6. Course schedule**

Date	Topic	Assignment
Day/Week 1	<ul style="list-style-type: none"> - Overview of the course - Epidemiological study designs (brief overview) 	-
Day/Week 2	<ul style="list-style-type: none"> - The development of contemporary Research Ethics - Principles of Research ethics 	NIH course on “Protecting Human Research Participants”: <ul style="list-style-type: none"> - Introduction - History - Code and regulations (http://www.fhi.org/training/fr/Retc/)
Day/Week 3	<ul style="list-style-type: none"> - Ethical issues in Research 	-
Day/Week 4	<ul style="list-style-type: none"> - Responsibilities of Research Ethics Committees 	NIH course on “Protecting Human Research Participants” <ul style="list-style-type: none"> - Respects for Persons - Beneficence
Day/Week 5	<ul style="list-style-type: none"> - Informed Consent 	NIH course on “Protecting Human Research Participants” <ul style="list-style-type: none"> - Justice - Conclusion
Day/Week 6	<ul style="list-style-type: none"> - Responsibilities of sponsors and researchers - Community participation in the research process - Professional responsibility 	-
Day/Week 7	<ul style="list-style-type: none"> *WRITTEN EXAMINATION *Research ethics course certificate 	Paper to be submitted one week after module IV