

Introduction to Research Ethics

Distance Education Online Course

<http://ccghe.org>

Course Syllabus

Welcome

Welcome. This course has been made available through joint efforts of the Johns Hopkins Center for Clinical Global Health Education, the Johns Hopkins Berman Institute of Bioethics and the Johns Hopkins Bloomberg School of Public Health. Funding has been provided by NIH Office of AIDS Research and Fogarty International.

Course Description

Introduction to Research Ethics provides an introduction to selected important topics in research ethics. This course introduces participants to ethics concepts as they apply to questions and challenges in conducting human subject research. The aim is to increase participants' awareness of and ability to reason through ethical issues that arise in the conduct of human subject research. The course also will discuss regulatory requirements relevant to international research (United States, India, and other relevant jurisdictions).

Objectives

Upon completion of the course you will be able to:

- Recognize the relevant ethical principles related to the conduct of human subject research
- Interpret and apply the ethics framework to moral problems encountered in research with human subjects
- Explore commonly encountered research ethics challenges and consider options for resolving them
- Identify and use applicable U.S. and Indian rules and regulations related to human subject research, including ethics committee requirements

Course Format

The content of this course is divided into 11 Lecture Modules, each corresponding to a grouping of lectures. All the required course work can be accessed from the Course Content (<http://moodle.ccghe.net/course/view.php?id=42>) page. The lecture sections are presented sequentially and should be completed in that order. Each of these sections combines audio presentation and slides—just like attending lectures in class – as well as the option to download the audio and/or slides separately. You may return to any previous section at any point and review its contents at your convenience. Below is a listing of each Lecture Module with the sections for each listed along with the time length of each presentation.

Pre and Post-Course Knowledge Assessments

There is a Pre- and a Post-Course Knowledge Assessment. The Pre-Assessment must be done prior to accessing any of the lecture material and the Post-Assessment should be taken after you have viewed all lectures to optimize your ability to do well. You may take each only 1 time.

Course requirements and Criteria for Earning a Certificate

Participants who complete the course according to the following guidelines will be able to print a Certificate of Achievement.

In order to receive a Certificate, the student must achieve the following:

1. Register to the website and enroll for the course online at www.ccghe.org

2. Achieve a Post-Course Knowledge Assessment score of 65% or better.
3. Complete the final course evaluation

Course Evaluation

At the end of this course, we urge you to complete the final course evaluation. The evaluation only takes a few minutes and it is valuable to us as a way to make program improvements for future courses. The current course is improved over past courses, because participants took the time to tell us how we are doing. We are grateful for their comments and suggestions.

**Funding for the development of this course is from NIH Fogarty International Center.*

Bioethics Course

Lecture 1 – History of Research Ethics: U.S. and South Asia

[Section A](#): Background (Kass) 19:19

[Section B](#): Landmark Cases in Research Ethics: U.S. History (Kass) 15:53

[Section C](#): History of Research Ethics in South Asia (Bhan) 20:56

Lecture 2 -- Ethics Principles

[Ethics Principles](#) 24:33

Lecture 3 – Ethics Framework

[Section A](#): Background and Introduction of Framework, Part 1 17:53

[Section B](#): Introduction of Framework, Part 2 4:02

[Section C](#): Case, Application of Framework Part 1 17:12

[Section D](#): Application of Framework Part 2 8:31

Lecture 4 – Ethics Committees

[Section A](#): What an EC Is and How It Functions (*Bhan*) 24:53

[Section B](#): Roles and Responsibilities, Requirements of EC (*Bhan*) 19:31

[Section C](#): Decision Making and Related Issues, DSMB (*Bhan*) 11:34

[Section D](#): Institutional Review Boards (IRBs) (*Kass*) 24:43

Lecture 5 – Informed Consent: What It Is and What It Includes

[Section A](#): Introducing Informed Consent 16:09

[Section B](#): Components of IC 23:19

[Section C](#): Summarizing the Key Issues in IC 9:29

Lecture 6 – Informed Consent: What Contributes to a Good Process

[Section A](#): Form 10:57

[Section B](#): Process 11:18

[Section C](#): Subject and Researcher Characteristics 11:10

Lecture 7 – Study Design

[Section A](#): Ethics Review 7:32

[Section B](#): Types of Trials 42:43

[Section C](#): Oversight 7:56

[Optional Section D: Design Choices \(Steven N. Goodman, MD, PhD\)](#) 18:08

Lecture 8 – Risk/Benefit Assessment

[Section A](#): Balancing Risks and Benefits 23:05

[Section B](#): Balancing Risks and Benefits (cont.) 13:17

Lecture 9 – Honesty in Science: Integrity and Authorship and Conflicts of Interest

[Section A](#): Definition Overview 19:20

[Section B](#): Mechanisms to Address COI: Individual Level 12:43

[Section C](#): Responsible Conduct of Research 20:50

[Section D](#): Good Clinical Practice 12:38

[Section E](#): Authorship 25:26

Lecture 10-- Privacy and Confidentiality

[Section A](#): Introducing Privacy and Confidentiality 13:17

[Section B](#): What Do the Guidelines Say on Privacy and Confidentiality? 13:29

[Section C](#): Challenges in Maintaining Privacy in Our Settings; Mechanisms to Address Challenges to Privacy and Confidentiality 18:02

Lecture 11 – Justice: Applied

[Section A](#): Fair Allocation: Population Level 17:27

[Section B](#): Fair Allocation: Individual Level 10:48