Ethical and Regulatory Aspects of Clinical Research

Department of Clinical Bioethics
Wednesday mornings 8:30 a.m. – 11:30 a.m.
Building 10/ Masur Auditorium
October 6 to November 17, 2004
With an optional 8th session on International Research, Dec. 8, 2004

Target audience for this course: MD and PhD scientists in the intramural program, research staff (including research coordinators, nurses, other support personnel), extramural program officers, and other interested parties in the NIH community. Skill level: aimed at those who are involved in conducting research as either principal investigators or members of the team.

Objectives:

1. Review the codes, declarations, and other documents that govern the ethical conduct of human subject research;
2. Review the critical elements of informed consent and their implementation in actual informed consent documents for clinical research;
3. Explore controversial issues relating to human subject research, including Phase I research, randomization, children in research, international research, etc;
4. Review the purpose of IRBs and provide IRB-like experience in reviewing research protocols, and;
5. Understand the experience of human subjects who have participated in research protocols.

Agenda:

October 6, 2004	**Session 1 – History of and Framework for Human Subject Research**
8:30-8:45	Pre-test Welcome- John I. Gallin MD, Director, Warren G. Magnuson Clinical Center; Associate Director for Clinical Research
8:45-9:20	Introduction to the course and Framework for the Ethics of Research with Human Subjects Ezekiel Emanuel, MD, PhD Chair, Department of Clinical Bioethics, NIH
9:20-9:30	Discussion
9:30-10:15	Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest John Arras, PhD Porterfield Professor of Biomedical Ethics University of Virginia

10:15-10:25 Discussion

10:25-10:40 **Break**

10:40-11:20 Do the Codes Apply to My Research Protocol? Nuremberg, Helsinki, the Belmont Report, CIOMS, and the Common Rule
Christine Grady, RN, PhD
Deputy Chair
Head, Section on Research Ethics
Department of Clinical Bioethics, NIH

11:20-11:30 Discussion

October 13, 2004 **Session 2 – IRB Review and Conflicts of Interest**

8:30-9:15 Conflicts of Interest
Lindsay Hampson, BA
Second Year Fellow
Department of Clinical Bioethics

9:15-9:25 Discussion

9:25-10:10 The Purpose and Function of IRBs: Successes and current challenges
Dale Hammerschmidt, MD
Director of Education in Human Subjects Protection
University of Minnesota

10:10-10:20 Discussion

10:20-10:40 **Break**

10:40-11:30 Mock IRB-
Dale Hammerschmidt, MD
University of Minnesota

October 20, 2004 **Session 3 – Special Subjects and Subject Selection**

8:30-9:10 Ethics of Phase I Oncology Research
Manish Agrawal, MD
National Cancer Institute

9:10-9:20 Discussion

9:20- 10:00 Subject Selection
David Wendler, PhD
Head, Unit on Vulnerable Populations
Section on Research Ethics
Department of Clinical Bioethics, NIH

10:00- 10:10	Discussion
10:10- 10:25	**Break**
10:25- 11:30	Participant Panel

October 27, 2004	**Session 4 – Ethical Issues in Research Design**
8:30-9:15	Clinical Care versus Clinical Research and the Therapeutic Misconception Howard Brody, MD Professor, Center for Ethics and the Humanities in Life Sciences Michigan State University
9:15- 9:25	Discussion
9:25-10:10	Ethics of Randomized Clinical Trials: Clinical Equipoise Robert Truog, MD Professor of Anesthesiology & Medical Ethics Harvard Medical School
10:10-10:25	Discussion
10:25-10: 40	**Break**
10:40- 11:20	Ethics of Placebo Controlled Trials Susan Ellenberg, PhD Director, Office of Biostatistics and Epidemiology Center for Biologics Evaluation and Research, FDA
11:20- 11:30	Discussion

November 3, 2004	**Session 5 –Informed consent and Children**
8:30-9:15	Practical Aspects of Informed Consent Alison Wichman, MD Deputy Director Office of Human Subject Research, NIH
9:15-9:25	Discussion
9:25-10:10	Informed Consent: What do the data show? Christine Grady, RN, PhD Deputy Chair Head, Section on Research Ethics Department of Clinical Bioethics, NIH
10:10-10:20	Discussion

10:20-10:45 Break

10:35-11:20 Research Involving Persons at Risk for Impaired Decision-Making
Don Rosenstein, MD
Chief, Psychiatry Consult-Liaison Service
Deputy Clinical Director, NIMH

11:20-11:30 Discussion

November 10, 2004 **Session 6 – Genetics, Stored Tissue, and HIPAA**

8:30-9:15 Ethical Issues in Genetics Research
Benjamin Wilfond, MD
Head, Section on Ethics and Genetics, Clinical Bioethics
Medical Genetics Branch, NHGRI

9:15-9:25 Discussion

9:25-10:10 Ethical Issues in the Use of Stored Tissue
Sara Chandros Hull, PhD
Head, Research Ethics
Bioethics Research Section, Medical Ethics Branch, NHGRI

10:10-10:20 Discussion

10:20-10:35 **Break**

10:35- 11:20 Privacy Rule and Clinical Research
(Health Insurance Portability and Accountability Act – HIPAA)
Mary McCabe, RN
Director, Cancer Survivorship Program
Memorial Sloan Kettering Cancer Center, New York

11:20-11:30 Discussion

November 17, 2004 **Session 7 – Research with Children**

8:30-9:15 Children as Research Subjects
Alan Fleischman, MD
Senior Vice President, New York Academy of Medicine

9:15-9: 25 Discussion

9:25-10:10 Pediatrics: what counts as minimal risk?
David Wendler, PhD
Department of Clinical Bioethics, NIH

10:10-10:20 Discussion

10:20-10:40	**Break**
10:45-11:30	Mock IRB – Pediatric Protocol Alan Fleischman, MD Senior Vice President, New York Academy of Medicine [

Extra session: December 8, 2004- Current topics in the Ethics of International Research

8:30- 9:15	Exploitation Alan Wertheimer, PhD John G. McCullough Professor of Political Science University of Vermont
9:15-9:25	Discussion
9:25- 10:10	Ancillary Care Henry Richardson, PhD Georgetown University
10:10-10:20	Discussion
10:20- 10:35	Break
10:35- 11:20	Post-trial benefits Reidar Lie, MD PhD Head, Unit on Multi-National Research, Section on Research Ethics Department of Clinical Bioethics, NIH
11:20- 11:30	Discussion

Speaker List
Ethical and Regulatory Aspects of Human Subject Research
October 6, 2004 – November 17, 2004 and December 8, 2004

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