# Ethics & Medical Research

## Research, Treatment & the Moral Obligations of Physicians

As you read the material for the next class, keep the questions below in mind. To answer these questions you will have to reflect critically on what you have read and possibly re-read important passages. Keep in mind that there are two basic kinds of information that you need to look for in the readings:

1. What are the main points or conclusions that an author accepts with respect to a particular issue?
2. What are the reasons, important considerations, and evidence that lead the author to accept that conclusion?

For our purposes, *it is information of the second sort that will be our primary concern* since our most basic task is to *evaluate the reasons and evidence* that are offered to support accepting one possible conclusion about an issue, rather than another.

Although I strongly suggest that you write out brief answers to these questions, you do not have to turn in written responses. You do, however, need to be prepared to speak intelligently to these issues in the next class meeting.

**Readings**

- Robert Levine, "The Nature, Scope, and Justification of Clinical Research: What is Research? Who is a Subject?" pp. 211–221.
- Benjamin Freedman, Abraham Fuks & Charles Weijer, "Demarcating Research and Treatment: A Systematic Approach for the Analysis of the Ethics of Clinical Research" (PDF on webpage).

**Questions**

1. What tensions does Levine see occurring between the moral obligations of clinical researchers and those of medical practitioners?
2. How does Levine define (or seem to define) the following key concepts, and how are they related to and/or different from each other:
   - Research,
   - Generalizable knowledge,
   - Treatment (or "therapy", or "practice"),
   - "Practice for the benefit of others",
   - Experimentation, and
   - Nonvalidated therapy (or "investigational" therapy, or "innovative" therapy, or "nonvalidated practice")?
3. How does one carry out the "intra-trial" analysis of interventions and subsequent "two-stage" review of risks that Freedman, Fuks, and Weijer propose? What distinguishes the therapeutic justification for an intervention from a research justification? Does this differ from the approach suggested by Levine, especially when it comes to nonvalidated treatments?
4. Why do Freedman and colleagues use their approach to justify that Dr. L could legitimately provide subjects with a one-page consent form rather than the six-page one that Dr. L plans to use?
5. What is "equipoise", and what role does it play in the approach by Freedman and colleagues?
6. What are the different "forms" of research that Freedman and colleagues recognize? What are the normative differences that separate them? Are these normative differences recognized by Levine?