Ethics & Medical Research

Problems with Informed Consent in the Research Context

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

- Dan Brock, "Philosophical Justifications of Informed Consent in Research", pp. 606–612.
- Paul Appelbaum & Charles Lidz, "The Therapeutic Misconception", pp. 633–644.

Questions

1. List out the various moral considerations that Brock believes underlies the informed consent requirement. Which moral foundation does Brock consider the most relevant, and how do his three specific requirements for valid informed consent (informed, voluntary, and competent) ensure that this moral foundation is satisfied?
2. Why is it important to distinguish competent from incompetent decision makers? What is the nature of this distinction? Where should the burden of proof about competency lie in the research context?
3. In general, what is the therapeutic misconception? What are the two forms of it specified by Appelbaum and Lidz? What are some examples of each? What encourages patient-subjects to have this misconception? Does it threaten the three specific requirements of informed consent given by Brock?
4. In light of concerns arising with the therapeutic misconception, what role (or weight) should informed consent play (or possess) as a safeguard for subject interests in clinical research?