

Ethics & Medical Research

Protection & Access in Participant Selection

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

- Leslie Meltzer & James Childress, "What is Fair Participant Selection?" pp. 377–385.

Questions

1. What was the view of just and fair participant selection in the Belmont Report and Common Rule? What was the rationale for this view? Why was this view challenged by HIV/AIDS activist groups? How was the view of just and fair participant selection further challenged by considerations of fair access to the results of medical research?
2. Why are minorities and the elderly underrepresented in clinical research? Why is doing this morally and scientifically problematic?
3. What happened during the Kennedy Krieger Institute lead paint study? What rationale did the court give for excusing the institute of wrongdoing and exploitation? How is this case similar to that of Willowbrook?
4. Why is there a concern of injustice and unfairness in international research? What is the proper balance between protectionism and access in this context?