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# Informed Consent and the Therapeutic Misconception: Clarifying the Challenge

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In their insightful review of the state of research ethics, Franklin Miller and Jonathan Moreno include a discussion of some "disturbing trends" in the literature on informed consent. They regard these trends as threatening an "unjustified erosion" in our commitment to informed consent as a requirement of ethical medical research. As the author of one of the articles discussed in this connection,[1] I am grateful for the opportunity to clarify some of the issues at stake in the debate. While I shall not try to do much more than that here, I agree with Miller and Moreno that these issues merit more sustained examination.

Let me begin by summarizing some important points of substantive agreement. Doctrinally, as it were, I agree with Miller and Moreno that the two core duties of informed consent are morally binding on the conduct of clinical trials: participation in clinical research should be strictly voluntary (consent) and investigators are required to disclose adequate information about the research to prospective subjects (disclosure). Philosophically, it seems that we also agree about two of the central inferences in my critique of the standard interpretation of informed consent. First, from the (apparent) fact that many subjects in clinical trials suffer from a "therapeutic misconception"[2] — in particular, they "systematically misinterpret the risk/benefit ratio of participating in research"[3] — it follows that they fail to exhibit adequate comprehension of the standard disclosure. Second, *if* adequate comprehension of the disclosure is a *necessary* condition of valid consent, then many prospective subjects should be excluded from participation in clinical trials. Enforcing this exclusion would bring enrollment in many valuable and otherwise ethical clinical trials near to a halt.

Where we disagree, of course, is in what to do with these inferences. Specifically, we disagree about whether adequate comprehension *is* a necessary condition of valid consent. I do not think it is, whereas Miller and Moreno (along with most everyone else) do. Yet, before we explore further points of difference, it will be instructive to dispel a misunderstanding of the structure of my argument — and hence, of its force — that may arise from Miller and Moreno's presentation.

At one point, Miller and Moreno warn against the erosion of informed consent "out of despair over evidence that patient-volunteers 'just don't get it.' " From this formulation, it is certainly possible to gain the impression that the challenge posed by the therapeutic misconception lies simply in a demonstration that adequate comprehension of the standard disclosure is very difficult to achieve. Adequate comprehension *is* very difficult to achieve (or so it seems), but it hardly follows without further ado — and here I agree with Miller and Moreno — that adequate comprehension is not required. Still less does it follow that investigators should therefore not bother trying to help prospective subjects to achieve it. However, that is not at all my argument.

My argument has a rather different structure. On the one hand, given the difficulty in achieving adequate comprehension of the standard disclosure in a suitable number of prospective subjects, a predictable consequence of enforcing a requirement of adequate comprehension will be to imperil clinical research of considerable moral value and importance. Hence, our *justification* for this requirement had better be pretty impressive, so as to warrant a moral cost of that magnitude. (I assume that the option of espousing, but not actually enforcing, such a requirement is morally untenable because utterly hypocritical). The real challenge posed by the therapeutic misconception, then, is to supply an affirmative answer to the question: Is there an adequate justification for the standard interpretation of informed consent, on which comprehension of the disclosure is a necessary condition of valid consent?

On the other hand, when we actually turn (under pressure from the therapeutic misconception) to examine alternative justifications critically, what we find is that none of them is adequate to warrant a requirement of comprehension. In my *Lancet* article, I mainly examined variations on the argument that comprehension is required to *protect* prospective subjects. I shall not rehearse my criticisms of that argument here, except to reiterate that they are restricted (as, therefore, is my position) to clinical trials in which the ratio of risk to *direct* benefit for individual participants is favorable. In any case, I accept that a more thorough examination of alternative justifications is in order (something I hope to pursue on another occasion). For the present, the important point is that the case against a comprehension requirement rests on the *absence of a sufficient justification* for it, rather than on the difficulties in satisfying it. The practical difficulties exposed by the therapeutic misconception merely serve to help define the scales in which the sufficiency of candidate justifications is weighed — weighed, and found wanting.

Finally, Miller and Moreno suggest that what "constitutes an adequate minimum of understanding and how it is to be assured are tasks for future work in research ethics." It seems to me that this puts the emphasis in the wrong place, especially on the first point. Investigating definitions of an "adequate minimum" of understanding presupposes that some adequate minimum is indeed required. In this context, that is to put the cart before the horse. The fundamental question is *whether* there is sufficient justification to require adequate comprehension of the disclosure in the first place. It is not clear what Miller and Moreno take that justification to be. Their emphasis (in rejecting equipoise) on the distinction between clinical research and medical care suggests an appeal to protection, but elsewhere in their article they (quite reasonably) deny that subject protection is the whole of research ethics. They also appeal to the "imperative of respect for persons." However, this imperative is symmetrical as between informed consent and informed refusal, whereas presumably no one thinks that failure to comprehend the disclosure invalidates a *refusal* to participate in clinical research. I am by no means suggesting that the nature of the justification for a comprehension requirement is something Miller and Moreno ought to have addressed, let alone settled, in their article. But I do think that addressing this question is a vital task for future work in research ethics, one that ought to be tackled before pondering what makes for an adequate minimum of comprehension.

Although I deny that adequate comprehension of the standard disclosure is a necessary condition of valid consent, I nevertheless agree that it is a goal worth pursuing.[4] Moreover, I also agree that investigators bear some responsibility for achieving it. I therefore agree with Miller and Moreno that it remains an important task to determine how adequate comprehension can be achieved in practice. The difference is that, in my view, this enquiry should be explicitly structured in terms of a *division of responsibility* between investigators and (prospective) subjects. What we need to define, more specifically, is a set of "reasonable steps" that investigators must take to ensure adequate comprehension on the part of subjects. It would be useful to open a debate on what steps are reasonable to require. However, implicit in the idea of only requiring investigators to take reasonable steps is that of a limit, beyond which responsibility falls on the prospective subject, and failure to achieve adequate comprehension does not invalidate consent. Unlike Miller and Moreno, I think we also have to acknowledge that there is some such limit on the investigator's responsibility to achieve adequate comprehension of the standard disclosure.

## NOTES

1. G. Sreenivasan, "Does Informed Consent to Research Require Comprehension?" *Lancet* 362 (2003): 2016-8.

2. P.S. Appelbaum et al., "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception," *Hastings Center Report* 17, no. 2 (1987): 20-4; S. Joffe et al., "Quality of Informed Consent in Cancer Clinical Trials: A Cross-sectional Survey," *Lancet* 358 (2001): 1772-7.

3. See Appelbaum et al., note 3 above; compare S. Horng and C. Grady, "Misunderstanding in Clinical Research: Distinguishing Therapeutic Misconception, Therapeutic Misestimation, and Therapeutic Optimism," *IRB* 25 (2003): 11-6.

4. See note 1 above.