Reviewer's report

Title: Human Subjects Protection Issues in QUERI Implementation Research

Version: 1 Date: 27 December 2006

Reviewer: Lee Green

Reviewer's report:

General

This manuscript addresses an issue of major importance in advancing implementation research as a science. The ethical principles and assumptions upon which the IRB system is based were designed for clinical trials and closely related forms of research. They are poorly adapted for implementation research, a fact which can paradoxically lead to IRBs being a serious barrier to organizations' ability to meet their ethical duty to improve the care of their patients. It is clear in many quarters, as the authors acknowledge, that both efficiency of research and effectiveness of human subjects protection requires more than minor adjustments in the existing system. The present authors' efforts fall into the adjustments rather than fundamental redesign category, but achieve both good science and sound human subjects protection remarkably well - albeit at a high and probably ultimately unsustainable cost.

The authors do very well at maintaining a constructive and optimistic approach to a situation that can engender a high level of frustration among researchers.

The explicit discussion of cost and personnel requirements is helpful.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The section "Learning to Communicate Implementation Specific Issues" is potentially very valuable, but unsatisfying in its present form due to its generality bordering upon vagueness. A concrete example (with identifying information removed, of course) involving interacting with two very different IRBs around the same project would help greatly.

The "Tools and Solutions" section to the "Local Differences" issue is also much too brief and general.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

There are a few places where copyediting is needed; I have eschewed copyediting at present however.

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Discretionary Revisions (which the author can choose to ignore)

For a recent pertinent reference that involved the VA system, the authors may wish to consider:

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.