APPENDIX A

Boundary Between Research and Practice Report: Methodology

In 2009, PRIM&R initiated a project to explore “ways of correcting the multiple difficulties that arise in applying the Common Rule’s definition of ‘research’ to health information producing activities at the borders of … biomedical [or behavioral] studies with human subjects that are the Rule’s central focus.” Confusion about how such activities should be reviewed and monitored can inhibit progress in these areas.

PRIM&R’s aim was to engage stakeholders in a series of interactive events to capture current practices and approaches which might offer practical methods that would inform new policy guidelines—both in and outside the Common Rule—on how to protect people in the evaluation and improvement of health care and the fulfillment of public health duties, on the one hand, and how to insulate the practice community from unnecessary encumbrances in the conduct of their day-to-day duties, on the other.

To accomplish this, PRIM&R convened a working group of its own board leadership, then expanded the activity to include selected leaders with long-standing engagement in PRIM&R’s on-going educational and public affairs activities (see list of participants in the first endnote of Final Report, and termed the effort the “Boundaries Project”.

This group, in turn, specified four domains that actively engaged in activities which cause difficulty in deliberations by institutional review boards (IRBs) and others in the human subjects protection world, diverting attention from other high priority work of already over-taxed IRBs and causing needless delays— even ill-will—among practitioners. These areas of focus were summarized as follows:

- “Innovative medical practice,” by which the steering committee wished to shed light on those aspects of clinical, medical, and surgical care which reflect the normal or usual diversity of approaches, particularly in ambiguous clinical situations or in those in which interventions are incompletely understood, but which, on balance, reflect the “art of medicine.”

- “Community based participatory research,” by which the steering committee wished to provide some help to those working in the broader patient care populations and, for that matter, community at large, particularly in ambiguous situations in which untested approaches at community engagement are required, but which, on balance, reflect the major ways in which communities can be engaged.

- “Public health practice,” by which the steering committee wished to clarify that research endeavors conducted under the name (or even aegis) of government public health might nevertheless cross over into the arena of efforts requiring human
APPENDIX A

subjects protection, but, on the other hand, generally require creativity in the face of a very diverse public health effort and many incompletely tested and tried approaches, including program evaluations which may collect data about interventions, but without significant individual human subject risks.

- “Quality improvement and quality assurance,” by which the steering committee wished to explore the conditions and criteria under which interventions initiated to advance clinical or community care, in the absence of clear precedent or applications in the specific settings, should be exempt from external review requirements.

To launch this effort, PRIM&R organized a one-day meeting of experts in the four relevant domains/fields to “initiate the development of recommendations for best practices, regulatory revisions, and new policy guidelines on how to protect people in the evaluation and improvement of health care and the fulfillment of public health duties” (Meeting Agenda, April 2011).

APRIL 2011 MEETING FORMAT

Following several conference calls and meetings, the steering committee, through an iterative nomination process, established a list of invitees to the “Boundaries” event. Individuals were selected based on their work in the areas of focus (i.e., clinical innovation, qualitative improvement/quality assurance, community based participatory research, and public health) and their experience dealing with ethical oversight of activities that lie at the margin of human subjects research.

In preparation for the meeting, staff invited prospective attendees to submit case studies that identified and described ethical questions related to the research-practice boundary with which they had had experience. These were provided as “cases-in-point” to the invitees, as a means of stimulating initial exploration of the conditions which might militate for or against requirement for formal ethical review.

Thirty one people attended the meeting. Following introductions and an overview of the day's agenda the group broke up into smaller working groups arranged by the four areas of study: clinical innovation, qualitative improvement/quality assurance, community based participatory research, and public health. Each group had as a facilitator a member of the steering committee, who was appointed to lead the discussion. The groups met in the morning for an hour and a half to discuss the attributes of the various activities within each topic that should prompt IRB review, review by an entity other than the IRB, or no prior review.

Following these breakout sessions the groups came back together to report on their progress. Based on these reports, the plenary group developed a matrix of characteristics in common from the four domains, relevant to ethical oversight. Finally, the group considered the implications of these characteristics for possible decision criteria for or against more formal ethical review of different types of activities within each area of focus.
2011 ADVANCING ETHICAL RESEARCH CONFERENCE

At the 2011 Advancing Ethical Research Conference, PRIM&R hosted a town hall meeting to discuss the Boundaries Project. In preparation for that meeting, PRIM&R invited attendees to submit examples of cases that illustrated their own struggles with ensuring ethical oversight of activities on the boundary between research and practice. From that meeting, PRIM&R collected a number of case studies, which are included in Appendix B.

PRIM&R BLOG FEEDBACK

In April 2012, PRIM&R’s blog, Ampersand, included a post about the Boundaries Project that solicited additional case examples. A number of examples were received in response. These cases are also included in Appendix B.

THIS REPORT

This report is based on minutes of the April 2011 meeting, analysis and input of the steering committee, and on the cases collected throughout the three years since the project was launched.