November 17, 2014

Jerry Menikoff, MD, JD
Director
Office for Human Research Protections
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

RE: Document 2014-25318, Draft Guidance on Disclosing Reasonably Foreseeable Risks in
Research Evaluating Standards of Care (79 Federal Register 63629)

Dear Dr. Menikoff:

Public Responsibility in Medicine and Research (PRIM&R), a nonprofit educational and professional
development organization dedicated to advancing the highest ethical standards in the conduct of
research, appreciates the efforts of the United States Department of Health and Human Services’ Office
for Human Research Protections (OHRP) to provide guidance on the disclosure of risks in research
evaluating standards of care.

Research evaluating standard treatments is becoming increasingly common as one means of improving
the efficiency and effectiveness of health care in the United States. Ensuring that patient-subjects are
adequately informed, protected, and respected in the course of such research is of critical import. To
that end, PRIM&R looks forward to sharing with OHRP its comments on the “Draft Guidance on
Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care.”

Given the breadth of opinions that surround research evaluating standards of care, we do not think that
the 60-day comment period will allow for the appropriately careful analysis and measured response
from all corners of the research ethics community that the guidance warrants. Our concerns are
exacerbated by the fact that the comment period encompasses both PRIM&R’s annual Advancing Ethical
Research Conference, which is attended by many stakeholders, and the holiday season, during which
many people with an interest in commenting are on leave from their jobs, effectively shortening the
comment period.

Therefore, PRIM&R requests that the comment period be extended to 120 days (ending on February 24,
2015) to allow all interested parties sufficient opportunity to craft thoughtful comments that will assist
the Federal government in this critical rulemaking process.

We thank you for your consideration of this request. If you have any questions or require any further
information, please feel free to contact me at (213) 740-2557 or PRIM&R’s executive director, Elisa A.
Hurley, PhD, at (617) 423-4112 or ehurley@primr.org.

Respectfully Submitted,

Alexander M. Capron
Board Chair

cc: Board of Directors
    Executive Director