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Jerry Menikoff, MD, JD
Director
Office for Human Research Protections
Department of Health and Human Services
Division of Policy and Assurances
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852


Dear Dr. Menikoff and Dr. Ostroff:


Since 1974, PRIM&R has been dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by serving individuals and organizations involved in biomedical, behavioral, and social science research, particularly the members and staff of institutional review boards (IRBs) and human research protection programs (HRPPs). With respect to this core group, we pursue two goals: (1) creating a strong and vibrant community of
ethics-minded individuals involved in research administration and oversight, and (2)
providing educational and professional development to promote the highest ethical
standards in research.

PRIM&R agrees with OHRP and FDA that additional guidance about the required content and
emphasis of IRB meeting minutes could benefit the research community, and we support
their effort to engage in public consultation on this issue through this request for comments.
We also recognize that OHRP and FDA are harmonizing their guidance in this area, and we
approve of such efforts to simplify the process by which IRBs who are answerable to both the
Department of Health and Human Services and FDA can comply with both sets of regulations.

Furthermore, PRIM&R agrees that documentation requirements can support human subjects
protections by fostering appropriate deliberations around matters most critical to protocol
review and approval. For instance, the recommendation that IRB minutes "include protocol-
specific information justifying the findings and determinations" serves to anchor IRB
discussion of specific study components to approval criteria and to the ethical principals
underlying them.

However, documentation requirements represent a double-edged sword. While broad
requirements can constructively drive substantive discussion of key subject protection issues
and actions, an excessive focus on “detailed” documentation will have unwanted
consequences and lead to wasted effort and less meaningful written records of IRB activity.
Too great a focus on minutes that optimize their auditability will lead to the replacement of
descriptive summaries with checklists and boilerplate language and thereby diminish their
value.

We therefore suggest that the final guidance provide additional clarification of expectations
with regard to the statements “minutes should be detailed enough for OHRP and FDA to be
able to determine compliance with the applicable regulations” and specifically, “the minutes
should summarize the IRB’s consideration of the approval criteria and include a
determination as to whether the criteria were met.”

For example, when documenting deliberations related to protocol approval or waiver of
consent, we believe it is not necessary for the minutes to document consideration of
how each criterion for approval or waiver under 45 CFR 46.111 or 45 CFR 46.406 or 45 CFR
46116 (d) is met. We assert that IRBs can effectively exercise judgment in determining how
best to summarize how its decision-making aligns with regulatory requirements.
Furthermore, the draft guidance includes the statement, “We recommend that IRBs document their findings in the minutes or elsewhere in the IRB records.” With regard to this statement, we believe the guidance should not suggest:

- that each set of minutes include documentation of the representative status for each member;
- that if consultants are present at the meeting, it is necessary to document in the minutes that they have not voted;
- that non-members or guests present at the convened meeting did not participate in deliberations or vote if this rule is otherwise specified in policy;
- that it is necessary to document in the minutes, if otherwise specified in policy, the description of how it will be determined that conditions are met each time the IRB approves a protocol with conditions, as indicated in the draft guidance.

We hope that you will find our input on this matter useful as you finalize this guidance. If you have any questions or require any further information, please feel free to contact PRIM&R through its executive director, Dr. Elisa A. Hurley at (617) 423-4112 or ehurley@primr.org.

Sincerely,

Susan Z. Kornetsky, MPH  David H. Strauss, MD  Elisa A. Hurley, PhD  
Chair, Board of Directors  Chair, Public Policy Committee  Executive Director

cc: Board of Directors