



March 1, 2010

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RE: PRIM&R's Comments on Proposed Rule on Informed Consent Elements, Docket No. FDA-2009-N-0592, RIN number 0910-AG32

Dear Sir/Madam,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) proposed rule on Informed Consent Elements announced on December 29, 2009 in the Federal Register, (Volume 74, Number 248, Pages 68750-68756.)

PRIM&R is a non-profit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served the full array of individuals and organizations involved in biomedical, social science, behavioral and educational research. PRIM&R's membership community includes professionals representing human subjects protection, animal care and use, and institutional biosafety programs, as well as researchers, institutional officials, government personnel, subject advocates, ethicists, policy makers, pharmaceutical and biotechnology leaders, and attorneys. Via a wide variety of conferences and courses, PRIM&R provides balanced, well-researched, and accurate information on the range of ethical and regulatory issues affecting research, while also offering access to certification, networking, and professional development resources.

PRIM&R supports efforts to fully inform potential research subjects of the risks, benefits and alternatives potentially encountered as a result of participating in research. PRIM&R also supports providing information related to the confidentiality and use of data collected for research purposes. Having said this PRIM&R has two serious concerns about the proposed rule.

1. The proposed rule sets forth the specific language to be included in the informed consent document and process. This approach is inconsistent with the other provisions of 21 CFR 50.25 which merely require the inclusion of certain information in the informed consent process and documents without dictating the precise language for each item of information to be included. Local institutions need to be able to present information in a manner that the local community will understand.

Requiring specific language denies the flexibility that is the goal and strength of local review.

2. The specific language dictated by the proposed rule to be required for inclusion in the informed consent document and process is extremely technical and uninformative to the average lay person. It does not come close to meeting the requirement that the consent process and forms should be created in such a way as to provide information to a lay person who has no knowledge of either medical or regulatory terms. Indeed, the proposed language is an example of what is wrong with consent forms and processes that are designed to primarily address regulatory concerns and compliance. We suggest that the solution is found in the above paragraph which suggests that local institutions be required to provide the information without the FDA dictating specific language.

Thank you again for the opportunity to comment on this proposal.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Joan Rachlin".

Joan Rachlin, JD, MPH
Executive Director
Public Responsibility in Medicine and Research

Cc: Board of Directors, Public Policy Committee