

# PRIM&R

PUBLIC RESPONSIBILITY IN  
MEDICINE AND RESEARCH

January 30, 2009

Michael A. Carome, MD  
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OHRP  
1101 Wootton Parkway  
Suite 200  
Rockville, MD 20852

RE: "Guidance on Discontinuation of Subject Participation"

*Submitted electronically to [discontinueparticipation@hhs.gov](mailto:discontinueparticipation@hhs.gov)*

Dear Dr. Carome,

On behalf of Public Responsibility in Medicine and Research (PRIM&R), we appreciate the opportunity to comment on the recent Draft Guidance on Important Considerations for When Participation of Human Subjects in Research Is Discontinued, 73 FR 231, pages 72804-72805, December 1, 2008.)

PRIM&R is an international, 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.

OHRP has requested comments on this draft which provides guidance on how to interpret the terms "participation" and "discontinuation of participation" in research. The guidance would also clarify (1) that investigators may continue to analyze already collected individually identifiable private information about a subject even when the subject's participation has been discontinued, and (2) that research may continue to involve human subjects even when the participation of all subjects has been completed or discontinued.

## Ongoing Duty of the IRB and Investigator

The draft guidance discusses the extent to which an investigator may continue to use, study or analyze already collected data following a subject's discontinued participation in research, but does not address the ongoing responsibilities that the investigator and IRB have towards such subjects. If subsequent to a subject's termination from the research, the investigator learns of new risks associated with the study, does that investigator/IRB have an obligation to contact former subjects? Take, for example, the case where latent risks associated with an experimental agent emerge after a subject's participation is discontinued. Additional guidance on the investigator's and IRB's duty to follow up with former subjects would reduce confusion on this point.

## IRB Review

The draft guidance does not address the question of when continuing review by the IRB may be discontinued. It is clear that even when the participation of all subjects has been completed or discontinued, the research is still subject to periodic continuing review by the IRB as long as the research continues to involve the analysis of individually identifiable private information. The question remains, however, when may it be determined that the *analysis* has been completed or discontinued, such that continuing IRB review is no longer necessary. The purpose of continuing review is to ensure that the research proceeds in accordance with the approved protocol, that the risks and potential benefits have not changed, and that subject safety continues to be protected in the manner originally approved by the IRB. If all activity related to the subjects and to their private data is completed or discontinued, is continuing review still necessary? For example, consider a study in which the participation of all subjects has been completed, and the researcher has completed his/her data analysis. The researcher decides to write a scientific article about his/her findings from the study. The process of drafting the article may require the review of previously collected data to verify conclusions. Will the research require continuing review at this stage, and during the time that it takes the researcher to complete the article? What about the period of time following publication of the article? If no further interaction, collection of data, or analysis is ongoing, continuing review would offer no additional protections for subjects, and would devolve into a purely bureaucratic function which ultimately reduces the effectiveness of a human research protection program.

PRIM&R recommends that this guidance include an explanation for when "data analysis" has been completed such that continuing review is no longer required. It would be helpful to researchers and to the IRB community to have a clearer understanding of when the research is no longer subject to this requirement.

## Informed Consent Process

PRIM&R recommends that the guidance include advice on how to inform subjects of the impact of ongoing risks associated with the research that may endure even after completion of, or withdrawal from the research. Specifically the guidance should advise researchers to include in the informed consent process:

- an explanation that the information collected about subjects during a research study may remain accessible to the researchers even after the subject is no longer involved in the study,

- an explanation of the future risks associated with latent side effects that may occur following discontinuation; and
- an explanation of the future risks associated with potential breach of confidentiality related to the accessible data.

Thank you again for issuing this draft guidance, and for the opportunity to comment on it.  
Respectfully Submitted,



Leonard Glantz, JD  
Chair, Board of Directors  
Public Responsibility in Medicine and Research

Cc: Board of Directors, Public Policy Committee