

OHRP Questions and Responses

Question 1:

For research involving subjects who are children initially, but become adults during the course of research, does consent of the subjects need to be obtained when the subjects become adults?

OHRP Response:

OHRP notes that informed consent should be viewed as an ongoing process throughout the research. When a child who was enrolled in research with parental permission subsequently reaches the legal age to consent to the procedures involved in ongoing research, the subject's participation in the research is no longer regulated by the requirements of 45 CFR part 46, subpart D regarding parental permission and subject assent. The investigators would need to seek and obtain the legally effective informed consent described in 45 CFR 46.116 for the now-adult subject for any ongoing interactions or interventions with the subjects because the prior parental permission and any assent are not equivalent to legally effective informed consent for the now-adult subject. The IRB could approve a waiver of informed consent under 45 CFR 46.116(d), if the IRB finds and documents that the required conditions are met.

Similarly, if the research does not involve any ongoing interactions or interventions with the subjects, but continues to involve human subjects (for example, only involves the continued storage of identifiable specimens for future research studies), then it would be necessary for investigators to seek and obtain the legally effective informed consent of the now-adult subjects, or for the IRB to consider, and if appropriate, approve a waiver of informed consent under 45 CFR 46.116(d) in order for the subjects to continue their participation in the research.

Question 2:

What is a suspension or termination of IRB approval of research and when do such suspensions or terminations need to be reported to OHRP?

OHRP Response:

(1) OHRP considers a suspension or termination of IRB approval to have occurred whenever the IRB issues a mandatory directive to an investigator in writing to suspend or terminate some or all activities being conducted under an IRB-approved research protocol. Such directives may be issued as a result of decisions made either by the IRB at a convened meeting or by the IRB chairperson who has determined that such action is necessary to eliminate apparent immediate hazards to subjects pending further review by the convened IRB. Such directives would include, but not be limited to, directives to suspend enrollment of new subjects and to suspend interventions or interactions in

previously enrolled subjects. Such suspensions should be reported promptly to OHRP even if the IRB or the institution determines that further investigation is needed to evaluate the circumstances that lead to the IRB's directive. Please note that with respect to reporting this type of action to OHRP, it does not matter what label the institution or IRB use to describe the action (e.g., IRB "suspension" versus "administrative hold").

(2) OHRP would consider a decision by an investigator, even if prompted by a verbal or written recommendation from the IRB chairperson or another institutional official, to suspend or terminate some or all activities being conducted under an IRB-approved research protocol pending further review or investigation by the IRB or other entity within the institution to NOT be a suspension or termination of IRB approval.

(3) For both (1) and (2) above, an institution must report promptly to OHRP any serious or continuing noncompliance or any unanticipated problem involving risks to subjects or others identified during any review or investigation by the IRB or other entity within the institution.

(4) For (2) above, an institution must report promptly to OHRP any subsequent suspension or termination of IRB approval that occurs as a result of any review or investigation by the IRB or other entity within the institution.