

Standard Operating Procedure For: Consent of minors at age of majority

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Purpose

The purpose of this standard operating procedure (SOP) is to provide a plan for research personnel to obtain the legally effective informed consent of research subjects who were enrolled in research as minors, and have now reached the age of majority (18).

Scope

This SOP is based on OHRP Guidance and New York State Law. This SOP applies to all minor subjects enrolled in research studies through the Division of Pediatric Infectious Disease at SUNY Upstate Medical University.

Plan

Unless the IRB determines that the requirements for obtaining informed consent can be waived, legally effective informed consent will be obtained for the now-adult subject for any ongoing interactions or interventions.

Subjects enrolled in clinical trials are listed on a spreadsheet maintained by the division administrative assistant. The spreadsheet tracks study numbers, next visit week due by week and date. The spreadsheet also lists the subjects' date of birth. The administrative assistant will notify the study coordinator when a subject is scheduled for his/her first study visit after the 18th birthday. The study coordinator will obtain consent from the subject (documented on the IRB approved consent form) and confirm that the subject is re-consented to the study at that time.

If the research does not involve any ongoing interactions or interventions with the subjects, but continues to meet the regulatory definition of "human subjects research" (for example, it involves the continued analysis of specimens or data for which the subject's identity is readily identifiable to the investigator(s)), then it would be necessary to seek and obtain the legally effective informed consent of the now-adult subjects. The IRB may consider, if appropriate, a waiver of the requirements for obtaining informed consent in order for the subjects to continue their participation in the research.