Mount Sinai

Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel
Mount Sinai Brooklyn
The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary
of Mount Sinai
Mount Sinai St. Luke's
Mount Sinai West

Program for the Protection of Human Subjects
Institutional Review Boards

Mount Sinai Health System
One Gustave L. Levy Place, Box 1081
New York, NY 10029-6574
T 212-824-8200
F 212-876-6789
irb@mssm.edu
icahn.mssm.edu/pphs

OBTAINING INFORMED CONSENT WHEN A MINOR ENROLLED IN RESEARCH ATTAINS 18 YEARS OF AGE

I. SCOPE OF POLICY:

In New York State, a minor turning 18 acquires the legal right to direct his or her own health care and participation in research activities. Previous parental permissions lose their validity. It is therefore necessary to consent subjects who were enrolled as minors in active research projects when they turn 18. These include projects that do not involve any ongoing interactions or interventions with the subject but continue to meet the definition of "human subject research," including those limited to a banking component where specimens or data are still being stored for future uses.

EFFECTIVE DATE: August 20, 2019

II. POLICY:

A. General guidelines:

If there has been no determinations to the contrary then subjects are presumed to be competent at age 18. If this is not so, incapacity has to be evaluated and documented, and consent by the appropriate next-of-kin/guardian must take place. If the subject has been adjudicated incompetent then as long as the original permission was signed by the correct person, it remains valid when the subject turns 18 and a new consent is not needed. Barring specific permission from the PPHS consenting should be accomplished within 2-3 months of turning 18.

B. The "Withdrawal Rule":

If a subject turns 18 and there is no consent obtained then the subject should be withdrawn from the project and their specimens and data handled per the protocol. Generally, this means the destruction of unused samples, and a request sent to return unused specimens already shared. If specimens and or data are already in use for an approved research project, those specimens and data can be maintained to complete that research that has already started, but new derivative subprojects and the like are not authorized.

C. Exceptions to the "Withdrawal Rule"

This exception can only be granted if a retention policy has been reviewed and approved by the IRB. This retention policy has to have been included in the parental permission and subject assent material, except in cases where subjects were never capable of giving assent.
A commonly requested retention policy is for the samples/data to be retained after a timely and unsuccessful good faith effort to locate the subject. This only possible if:

- The ongoing use of those samples/data should be restricted to whatever future use was chosen at the time of the original parental permission (e.g., not agreeing to unrelated uses).
- The samples/data should be retained without any link to identifiers, i.e. they are permanently anonymized.
- Evidence of the good faith effort should be retained in the research files, and such attempts were made using multiple techniques (e.g. snail mail, email, EPIC MyChart, etc.).
- If the parental permission or assent, where obtained, did not discuss the retention plan then the subjects and their data/specimens should be considered withdrawn at age 18.