



MCW Guidance on Obtaining Age of Majority Consent

This document aims to provide guidance for research teams on MCW's expectations about obtaining consent once a minor subject reaches the age of majority.

DEFINITIONS:

Human subject: A living individual about whom an investigator (whether professional or student) conducting research:

- f* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or;
- f* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- f* An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 56.102)

Identifiable private information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46.102)

Requirements for Age of Majority Consent

When a minor is a human research subject and reaches the age of majority while enrolled in a research project, consent from the subject is a requirement of the regulations. Below are general recommendations for how to address this requirement for varying types of projects:

Projects utilizing full informed consent	A plan for how subjects will be consented with the approved consent form upon reaching the age of majority must be provided in the eBridge application. Either a full consent form or an addendum can be utilized depending upon the research activities still occurring.
Projects granted an alteration of consent	A plan for how subjects will be approached for continued participation upon reaching age of majority must be included in the eBridge application. Generally, the plan should be equivalent to the initial method (e.g. if an informational letter was provided, it would be expected that another informational letter will be sent).
Projects without direct contact	A project without direct contact will likely be granted a waiver of assent and parental permission upon initial approval, so a waiver

	of consent should also be requested if subjects will be reaching the age of majority while identified data is being used.
Exempt Projects	If a project qualifies for exemption as determined by the MCW IRB, a waiver of consent for subjects who reach the age of majority would generally not be required since consent is not required for most exempt projects.

Access to Identified Data: Although contact may have ceased with a research subject, that subject is still considered enrolled in a project if the subjects data is identified in any way. Consent of the subject must be sought in most circumstances.

Tracking Methods: The MCW HRPP does not have specific requirements for how subjects should be tracked when a research team will re-approach subjects at the age of majority. The IRB will evaluate each plan within the context of the project and population. Common methods are 1) monthly reports of research logs/spreadsheets to track birthdates; 2) sending annual birthday postcards to continue contact over time; and 3) For projects where subjects are actively participating, birthdates can be checked prior to a subjects next appointment so subjects can be consented at that time.

Failed Attempt at Consent: If a subject cannot be contacted according to the previously approved contact plan, it is possible that age of majority consent can be waived in certain circumstances. This is only allowable when the team has requested a waiver of consent within eBridge, and it has been granted by the IRB.

Example 1: A project is seeking to consent subjects at the age of majority with a full consent form. Language should be included at the time of initial consent that re-contact will occur once a subject reaches the age of majority and that data/biospecimens will be kept after a certain number of failed contact attempts.

Alteration of the consent process: A project was initially granted an alteration of consent using an informational letter and is seeking to re-contact subjects at the age of majority with another informational letter. Language should be included in the initial letter that re-contact will occur once a subject reaches the age of majority and that data will be kept after a certain amount of time with no contact from the subject.

Consent for Banking

When MCW provides IRB oversight for another institution or entity, MCW policies will apply in addition to any requirements of the home institution.