This document aims to provide guidance for research teams on CW's expectations about obtaining consent once a minor subject reaches the age of majority. These expectations, and CW policies must be complied with regardless of the IRB of record reviewing the research.

DEFINITIONS:

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

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102)
- 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)

Once a minor reaches the age of majority (the subject is now an adult – 18 years old in Wisconsin), if any research activities will continue for that subject, you will no longer have legally effective parental permission (considered the equivalent of informed consent in the case of a minor) or a valid HIPAA authorization. Research activities include accessing or using identifiable data or specimens for analysis or verifying information. The assent provided by the child before he/she turned 18 is no longer relevant, even if assent was provided on the parental permission form or on an assent form. Individuals enrolled as minors with parental or guardian permission who are now adults, must now provide their own legally effective consent and HIPAA authorization, unless the IRB of record and the Children's Privacy Board determines that a waiver of informed consent and waiver of HIPAA authorization can be granted.

There is the possibility that previously enrolled subjects will reach the age of majority after study closure, but during the 10-year records retention period (CW policy – **Research Records: Record Retention for Human Subjects**) during which time identifiable data may be stored. The assumption is that there would be no access of the stored data in the future, prior to destruction at the end of the retention period. In this case, consent and HIPAA waivers would not be needed. However, if the PI anticipates the need to access or use the identifiable data after study closure, then the study would need to be reopened (and overseen by an IRB) and consent and HIPAA authorization, or waivers if appropriate, would then be needed for any subjects who have reached the age of majority.

For any research that has oversight by an IRB, **the PI must describe in the submission the plan to address consent and HIPAA authorization for any minor subjects who may turn 18 while still considered a human subject.** The plan proposed for obtaining consent and HIPPA authorization of subjects who reach the age of majority will vary depending on the nature and design of the study, the subject population and at what point individual subjects are at in the research. However, **this plan**

should be considered while designing the research and must be described in the initial submission to the IRB. The proposed plan can, and should, contain a combination of options to cover any of the scenarios possible for the particular research.

General recommendations/expectations of Children's Wisconsin for different scenarios are listed below and the PI should consider when planning and submitting a project for approval which scenarios may apply and describe the plan for each of these to obtain IRB approval for that plan. If a situation arises for which the PI did not describe and get previous approval for the consent plan, then an amendment must be submitted to obtain that approval.

The default expectation is to obtain and document consent and HIPAA authorization from the now adult subject when possible. The method to do this generally should match the method approved for obtaining and documenting parental permission for a minor subject.

For example:

- If a **full parental permission** form was used, then a full consent should be used. Depending on the research activities still occurring it may be appropriate to use a consent addendum to describe the research activities in which the now adult subject is still participating.
- If an **alteration of parental permission** was granted for the project, the plan for the now adult subject should be equivalent (e.g. if an informational letter was provided to the parents/guardian then another informational letter should be provided to the now adult subject)
- If a **waiver of assent/parental permission/HIPAA** authorization was initially granted or is being requested for the project (for example records review projects), waivers should also be requested for those subjects who may turn 18 while still considered a human subject.
- If a **project qualifies for exemption**, 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.

<table>
<tr><th colspan="2">When Consent and HIPAA authorization for the now adult subject should be obtained and documented</th></tr>
<tr><td rowspan="3">There are continued research interventions/procedures including:
• access, collection, use/analysis, or storage of identifiable data and
• there is direct contact with the now adult subject, or
• the subject is reachable via the last known contact information Note: third parties, including parents, may not be contacted after a subject turns 18 to obtain contact information for the now-adult subject.</td><td>It is recommended that consent and HIPAA authorization be obtained at the next study visit if there is still direct contact with the subject</td></tr>
<tr><td>Subjects who are no longer seen in person should be contacted as soon as possible after turning 18 to obtain their consent and HIPAA authorization. This may be via an in person interaction or via a remote consent process (by telephone and encrypted email or telephone and standard mail).</td></tr>
<tr><td>Either a full, currently approved, consent form or an addendum can be utilized depending upon the research activities still occurring, (for example, if subject participation is limited to long term follow-up the addendum could be used)

If an addendum consent will be used, this must be submitted for IRB approval prior to use.

The subject must also be provided with a copy of the consent document(s) most recently signed by his/her parent or legal Guardian.

The stand-alone HIPAA authorization form may be used for studies involving PHI.</td></tr>
<tr><td></td><td>Research activities, including using or accessing identifiable data, will cease until consent and HIPAA authorization is obtained.</td></tr>
<tr><th colspan="2">When a waiver of consent/HIPAA authorization should be requested/may be appropriate</th></tr>
<tr><td>• There is no longer regular contact with subjects and subjects are no longer reachable (lost to follow-up, contact information is not known or available). Note: third parties, including parents, may not be contacted after a subject turns 18 to obtain contact information for the now-adult subject.
• Waivers of assent/parental permission/HIPAA authorization were initially granted for the project</td><td>The regulatory criteria for a waiver must also apply in order for this to be granted

The expectation is that researchers make attempts to contact a now adult subject, if there is contact information, and describe this in the age of majority plan.</td></tr>
</table>

SPECIAL CIRCUMSTANCES:

Subjects who have turned 18, have impaired decisions making capability, and have a court-appointed Guardian/Legally Authorized Representative (LAR)

The Guardian/LAR must provide consent and HIPAA authorization on behalf of the subject when the subject reaches the age of majority (18). Any previous permissions are no longer in effect when the subject turns 18, even if the same person who gave permission for their participation when the subject was a minor is the same person who is now their Guardian/LAR once the subject turns 18.

For example, if a parent provided parental permission when the subject was a minor, and that same parent is now an appointed Guardian for the now adult subject due to subject's lack of capacity, that parent must still provide consent and HIPAA on behalf of the subject now that the subject is 18.

The PI must verify status in terms of who has been appointed the subject's Guardian/LAR is and the scope of the Guardian/LAR's authority as appointed by the court. This can be tricky, so we suggest you seek guidance from the CW HRPP office.

Follow the same guidelines as above with a subject's Guardian/LAR in seeking consent or waivers, depending on the phase of subject's participation and the Guardian/LAR's availability to provide consent and HIPAA authorization.

Data has been sent to a sponsor/bio/data repository and is still identifiable

Once data have left the institution, in accordance with the subjects' documented written authorization, and no other research activities will be conducted, the local institution's oversight is complete and consent/HIPAA authorization or waivers do not need to be sought by the institution.

Consent for Banking at Age of Majority

where samples and/or identifiable data are collected before the child turned 18 and continued use meets the definition of "human subjects research" (for example, continued use of samples or data for which the subject's identity is readily identifiable to the investigators or ongoing collection of identifiable information) the now-adult subject should provide consent and HIPAA authorization for the continued use of the samples/data. The rights and welfare of subjects whose data have been "banked" are more difficult to safeguard than the rights and welfare of subjects participating in focused studies. For this reason, the IRB is generally reluctant to waive the informed consent process for "banking activities," so age of majority consent is typically required.

If it is not possible to obtain consent from such a subject, and not practicable to conduct the research without the waiver, the IRB may provide a waiver of informed consent and HIPAA authorization in certain limited circumstances.

Considerations for Single IRB, Reliance Agreements, and Deferrals

When IRB oversight for research occurring at CW is deferred to another IRB, whether MCW or another external IRB, CW's HRPP and institutional policies and guidance still apply and must be followed in addition to any determinations of the reviewing IRB.

A waiver of informed consent and HIPAA authorization will be considered in those cases where a subject's continued participation constitutes no more than minimal risk and meets the other requirements for waiver under 45 CFR 46.116(d), including the requirement that the "research could not practicably be carried out without the waiver." Such a waiver may be considered at the time of initial or continuing review or during a subsequent amendment. Factors that may make it impracticable to obtain consent from the now-adult who was enrolled as a child, and therefore would support a waiver, include:

- if there is no ongoing contact or there was never direct contact with subjects
- the number of subjects,
- length of time since first enrolled, and
- ability to locate subjects.