Guidance
Obtaining Consent for Continued Participation in Research by a Young Adult Who has Reached Age 18

Once a minor reaches the age of majority (the subject is now an adult), if research activities will continue for that individual, you will no longer have legally effective parental permission or HIPAA Authorization. Research activities include accessing or using identifiable data or specimens for analysis or verifying information. Children's Wisconsin (Children's) policy *Institutional Review Board (IRB) Assent* requires that individuals enrolled as children with parental or Guardian consent must be consented and provide HIPAA Authorization when they become adults unless the Children's IRB and the Children's Privacy Board determines that a waiver of informed consent and HIPAA Authorization can be granted.

If a child turns 18 while research activities or interactions are ongoing or while identifiable data or specimens are still being accessed or used by the study team, the now-adult subject must be consented and provide HIPAA Authorization for his/her participation to continue. The assent provided by the child before he/she turned 18, even if assent was provided on the parental permission form or on an assent form, is not legally valid consent.

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.

Possibilities include:

Subjects for which there are continued research interventions/procedures after turning 18
Consent and HIPAA Authorization for continued participation in the research will be sought for these subjects as soon as possible after subject turns 18. It is recommended that consent and HIPAA Authorization be obtained at the next study visit. Research activities, including using or accessing identifiable data, will cease until consent and HIPAA Authorization is obtained. • Investigators should use the current Children's IRB-approved consent and HIPAA Authorization form to obtain consent from the now-adult subject.

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Subjects who have completed all research interventions/procedures prior to turning 18 but their identifiable data or specimens may continue to be collected, used or accessed	

There is regular, in-person contact with the subject such as for follow-up visits.	Subject will be consented and provide HIPAA Authorization in person as soon as possible after turning 18. Research activities, including using or accessing identifiable data will cease until consent and HIPAA Authorization is obtained.
	
	• Investigators may use the current Children's IRB-approved consent and HIPAA Authorization form to obtain consent and HIPAA Authorization from the now-adult subject.
	
	• Investigators may also choose to use a separate consent for continued follow-up participation (for example, a clinical trial that remains open for long-term follow-up only). A written consent example begins at the end of this document.
	
	  • The separate consent 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.

There is no longer regular, in-person contact with the subject, but the subject is reachable.	Subject will be contacted as soon as possible after turning 18 to be consented and provide 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) Research activities, including collecting, using or accessing identifiable data will cease until consent and HIPAA Authorization is obtained.

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	• Investigators may use the current Children's IRB-approved consent and HIPAA Authorization form to obtain consent from the now-adult subject.
	
	• Investigators may also choose to use a separate consent for continued follow-up participation (for example, a clinical trial that remains open for long-term follow-up only). A written consent example begins at the end of this document.
	
	  • The separate consent 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.

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).	There must be an IRB approved consent waiver and partial HIPAA waiver in place for these subjects in order to continue to use or access identifiable data or specimens. **OR** All subject data and/or specimens must be stripped of all identifiers (and no code or key that allows data or specimens to be linked back to a specific subject).

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Subjects who have turned 18, have impaired decisions making, and have an 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. Verify status in terms of who has been appointed the subject's Guardian/LAR is and the scope of the Guardian/LAR's authority. Seek guidance from the HRPP office if needed. **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.**

Study is closed, but data has been sent to a sponsor/bio/data repository and is still identifiable
Once data has left the institution, in accordance with the subjects' 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.

A waiver of informed consent and HIPAA Authorization will be considered in those cases where a subject's continuing 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 consent an adult who was enrolled as a child, and therefore would support a waiver, include if there is no ongoing contact, the number of subjects, length of time since first enrolled, and ability to locate subjects.

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In situations such as biobanks or data registries, where samples and/or identifiable data are collected before the child turned 18 and continued use meets the definition of "human subject 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. If it is not practicable to re-consent such a subject, the IRB can provide a waiver of informed consent and HIPAA Authorization in certain circumstances. If there is no ongoing contact and the samples/data are de-identified by stripping the data of all identifiers and deleting all links between any individually identifiable data and the samples/data, continued use would not require consent and HIPAA Authorization from the now-adult subject.

Example Cover Letter to include with Consent for Continued Participation in a Research Study: Long-Term Follow-up Only

To: Subject Name

RE: STUDY NAME
SUBJECT'S STUDY ID #

Enclosed are documents for you to choose whether or not you wish to continue participating in a research study which you were enrolled to as a child. As these forms indicate, your parent(s)/guardian(s) provided consent and HIPAA Authorization for you to participate. Now that you have turned 18, we would like to obtain your consent and HIPAA Authorization for continued participation in this study.

We have also enclosed the most recent form(s) signed by your parent(s)/guardian(s) for you to review. At this point in time, the active participation portion of the study has ended and we are collecting information on how you are currently doing or accessing or using information that was already collected from you. The purpose of contacting you now will be described further in the attached form(s).

Please review the form(s) signed by your parent(s)/guardian(s) when you were originally enrolled on the study and the new form(s) explaining what will be happening going forward.

Whether or not you continue to be in this study is completely up to you. You can tell us if you do or do not wish to continue participating on the enclosed form(s). Regardless of your decision, we would appreciate you returning the completed form(s) to us for our records. A signed copy of the form (s) will be sent to you for your records.

Your participation up to this point has already provided valuable information, thank you.

Sincerely,

PI Name
Principal Investigator

Enclosures:
- Consent for Continued Participation in a Research Study
- HIPAA Authorization Form
- Copy of Consent Form(s) and HIPAA Authorization(s) Signed by Parent/Guardian

Example

CONSENT FOR CONTINUED PARTICIPATION IN A RESEARCH STUDY

TITLE:

PRINCIPAL INVESTIGATOR:
PHONE:
ADDRESS:

SPONSORS:

You are currently taking part in a research study. Permission for you to take part in this research study was given by one of your parents/guardian. Now that you have reached the age of majority, we are asking for your consent for continued participation in this research study. The age of majority means you are considered an adult enough to sign legal contracts and consents for yourself. This form will serve as the consent form for your continued participation in the study as an adult. **A copy of the consent form most recently signed by your parent/guardian is enclosed for your reference.**

You are currently in the follow-up phase of this study. Follow-up means that you have already completed the initial portion of the study (*describe as appropriate, for example: treatment in studies which have a treatment component, or sample submission from diagnosis/treatment for studies which classify and/or bank tissue specimens*). Follow-up means we still collect medical information about you to follow the long term course of your disease and treatment.

Medical Information (study data) about you is being sent to the *insert sponsor name***,** the sponsor of this study. In order to allow us to continue to send information about your current health, you will be asked to sign a separate form to authorize the use and sharing of new health information required for this study.

If study involved biospecimen collection, add: Blood or tissue samples may have already been sent for research testing as part of this study. If your samples can be identified as belonging to you and you prefer not to have the study doctors save or use your samples for future testing, you should notify us that you would like those samples thrown away.

At any time, you may ask for a summary of the study results. However, it may be several years after you take part in this study before the study is completed and the results are available.

WHAT WILL HAPPEN IF I WANT TO WITHDRAW MY PERMISSION IN THE FUTURE?
You can change your mind at any time and withdraw your permission. If this happens, you must withdraw your permission in writing. This can be done by contacting *insert contact information*. You should request a new copy of this form and fill it out by checking “I do not agree to continue” and sign and date the new form. Also, you can send a letter informing us of your wish to withdraw consent. However, researchers may continue to use health information that was provided before you withdrew permission.

If you sign this form consenting to stay on the research study, but later change your mind and withdraw permission, you will be removed from the research study at that time. This means that researchers will no longer be contacting you, or your doctor’s office, to collect follow-up information.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study, contact *insert contact information*.

If you have any questions about your rights as a research participant or any complaints that you feel you cannot discuss with the investigators, you may contact the Children's Hospital of Wisconsin Human Subject Protections (IRB) Office, 999 N 92nd Street, Wauwatosa, WI 53226 or (414) 337-7133.

Please sign below to indicate whether or not you would like to continue your participation in this study. After you have signed the form, please return it to us in enclosed, stamped, self-addressed envelope. Even if you do not agree to continued participation, we would appreciate you signing and returning the form to complete our records.

Whether or not to participate is totally voluntary and up to you. Your past participation has already provided valuable information which can be used to *add description here, for example: improve the diagnosis and treatment of childhood cancer* in the future.

Sincerely,

Insert PI's name

Documentation of consent or withdrawal of consent to continue to participate in the research study:

Please check one of the boxes below.

☐ I **AGREE** to continue my participation in this research study.
- I have been given a copy of the consent form most recently by my parents/guardian. I agree to remain in this study and have signed the enclosed HIPAA Authorization form to have my personal health information collected for research purposes and information on my medical health submitted to the sponsor of the study. I understand that I can change my mind about participation at any time.

☐ I **DO NOT AGREE** to continue my participation in this research study.
- I am withdrawing my consent for participation in this study. I understand that no further personal health information will be collected for research purposes, and that no more information on my health will be submitted to the sponsor of the study.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

If the study included biospecimen collection, add the following and indicate whether all or some samples remain identifiable or if identifiers have been removed.

Future use of biospecimens collected for this study:

During the time you have been in the study, biospecimens (such as blood or tissue) may have already been sent for research testing as part of this study.

☐ Biospecimens were collected for this study but direct identifiers were removed.

- If your samples were collected and the direct identifiers were removed, the researchers have no way of determining which stored sample is yours. You will not be able to withdraw them from being used for future research.

☐ Biospecimens were collected for this study and can still be identified as belonging to you.

- If your samples can be identified as belonging to you (identifiable), you can decide whether you will allow researchers to continue to save or use your biospecimens for future research. Please check one of the boxes below

☐ I **AGREE** to continue to allow researchers to use my identifiable biology samples for research purposes.

- I understand that I can change my mind about participation at any time, and that samples that have already been used cannot be retracted.

☐ I **DO NOT AGREE** to have my identifiable biology samples stored for future research purposes.

- I request that my biology samples be destroyed at the facility where they are presently being stored. I do understand that biology samples that have already been used cannot be destroyed.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

Research Representative's Statement

I have explained this research study to the subject and have answered any questions he/she had.

_____ _____

Signature of Authorized Research Representative Date

_____ CHW IRB #*xxxx*

Printed Name and Title of Research Representative Protocol Number