Children's Local Context
Consent Language Module

DIRECTIONS

This document contains Children's Wisconsin local language requirements for when Children's is a participating site in a multi-center reliance project. The below consent language should be maintained (if utilizing a Children's or MCW consent template) or inserted **using tracked changes** (if utilizing the IRB of record model consent template) as is appropriate in the context of a particular study.

CHILDREN'S WISCONSIN LOCAL CONTEXT LANGUAGE

Children's Wisconsin HRPP Contact Information

- ⇨ The following statement is included if the project is occurring at Children's Wisconsin: "If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call Children's Wisconsin Human Research Protection Program Office at 414-337-7133."

HIPAA Authorization Kept in Medical Record Language

- ⇨ The following statement is required if the project is occurring at Children's Wisconsin: "A copy of this signed consent/assent and HIPAA authorization will be placed in your Children's Hospital medical record."

Abuse Language

- ⇨ The following statement is included if the project has the possibility to uncover abuse (e.g., from a physical exam for research purposes): "The researcher is required by law to report child abuse or neglect (or suspicion of abuse or neglect) if you mention it to the researcher or if it is suspected."

Pregnancy or Reproductive Health Testing Language (NEW 02/11/2026)

- ⇨ The following statement is included if the project has the possibility of pregnancy or reproductive health testing (including to confirm inclusion or exclusion criteria): "Please note that because of Wisconsin law and your age, the researchers [may/will not] share your child's pregnancy test results with your parents during the study without your child's permission when the test is performed at Children's Wisconsin."

- ⇨ The following statement is included if the project involves at-home pregnancy testing: "A pregnancy test will be performed to ensure your safety during this study. You will be given a home pregnancy test kit and instructions on how to use it. If the test is positive, you [may/will] be withdrawn from the study, and we will discuss next steps for your care. Because it is a home pregnancy test, parents/guardians [may/will] become aware of a positive pregnancy test result."

Blood Testing Language

- ⇨ The following statement is included if the project includes blood testing procedures: "Results of your blood test will be released only to authorized persons as governed by Wisconsin law. A list of persons to be notified and reasons that will cause release of your blood test is available upon request."

Research-Related Injury Language

Standard Language

- ⇨ The following language is included if the project has the possibility of research-related injury: "Emergency medical treatment for injuries caused by your participation in this research project will

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be arranged for you. You or your health insurance may be billed for the costs of this emergency treatment. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer may be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the <researchers/ research doctors/ research director> right away. Contact information: <PI>, <telephone number>.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence."

Alternative Language (For Projects Where the Sponsor is Willing to Pay)

- ⇨ The following language is included if the project has the possibility of research-related injury ***and*** the sponsor is willing to pay for injury (look for the template change request in the submission): "If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the study doctor as soon as possible. You will not have to pay for medical treatment of any unexpected illness or injury that is caused by your participation in this study. There is no plan to pay you for anything besides the cost of medical treatment. There is no plan to pay for lost income or any non-medical costs that might result from the illness or injury."

Age of Majority Language

- ⇨ The following statement is included if the project has the possibility for minors to reach age 18: "You will be asked when you turn 18 years old if you would like to continue to participate in this study. If you do you will need to sign a new form."

Subject Choices and Optional Research

- ⇨ If the consent documents contain choices (e.g., opting-in for future research), subjects must indicate their selection using their initials instead of a checkmark.

Assent-Specific Local Context Language

The following statement is required if the project is occurring at Children's Wisconsin: "A copy of this signed consent/assent and HIPAA authorization will be placed in your Children's Hospital medical record."

For NCI CIRB and NMDP studies, please refer to the separate boilerplate language documents for the applicable required language and instructions.

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Consent/Assent Signature Blocks for Use in Model Consent Forms:

Note: These signature blocks should be used as written and the consenter should mark off the reason that assent or the second parent signature is not obtained.

Assent of Minor Subject (17 years old or younger)		
Name of Minor Subject *please print*	**Signature of Minor Subject**	**Date or Date/Time**
If child's assent is **not** obtained above, please indicate reason below (check one): ☐ Assent is documented on a separate IRB-approved assent form ☐ Child is under the required age range for assent ☐ The IRB granted a waiver of assent, please specify:_____		
Consent of Parent(s)/Guardian(s) /Legally Authorized Representative of Minor Subject		
Name of Parent/Guardian/Legally Authorized Representative *please print*	**Signature of Parent/Guardian/Legally Authorized Representative**	**Date or Date/Time**
Name of Parent/Guardian/Legally Authorized Representative *please print*	**Signature of Parent/Guardian/Legally Authorized Representative**	**Date or Date/Time**
Permission of the second parent not obtained because (*select all that apply*): ☐ Not required by the IRB (Risk Level 46.404 or 46.405) ☐ Other parent is deceased ☐ Other parent is unknown ☐ Other parent is not reasonably available: Specify _____ ☐ Only one parent has legal responsibility for the care and custody of subject.		