HUMAN RESEARCH PROTECTION

External IRB reliance: Hennepin Healthcare localized language for external consent templates

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Resource type GUIDANCE

Applicability: Relying on an external IRB (i.e. not the Hennepin Healthcare IRB) for IRB review and approval. In general, the study sponsor or lead site is responsible for creating the template consent form(s). To comply with the policies and requirements of HHRI's Human Research Protection Program, site-specific consent documents for Hennepin Healthcare must include applicable language, as described below.

Instructions: This guidance provides instructions on how to edit site-specific consent form template(s) to incorporate language required by HHRI policies and Minnesota state law. The request for IRB reliance submitted to the HHRI IRB should include the Hennepin Healthcare site-specific consent(s) with tracked changes to show the applicable required language from this guidance.

☐ Hennepin Healthcare Research Team and Research Site Information

The template consent form will have likely have placeholder sections to insert Hennepin Healthcare specific information such as contact information for the research team and the name of the institution. These sections include contact information for the Hennepin Healthcare PI and a 24-hour number participants can call in the event of an emergency.

☐ HHRI Human Subject Research Office Contact: Who should participants call with questions, concerns, or complaints?

If the consent template asks for local contact information for someone other than the study team for questions, concerns or complaints about the research, the following **out-of-study contact information** should be included. Example:

> If you have any questions, concerns, or complaints about the study or your rights as a subject in this study and want to talk to someone other than the Hennepin Healthcare Research Team, you can call the Hennepin Healthcare Institutional Review Board office at (612) 873-6882.

Note: The consent template provided by the lead site/study sponsor may already include the contact information for the external IRB; this is acceptable and must be retained.

☐ Confidentiality

The Hennepin Healthcare site-specific consent(s) should include language referencing Hennepin Healthcare in the section of the consent often entitled: *Confidentiality*; *What about my privacy*? or *What happens to the information collected for the research?* Any parties missing from the list of organizations or people who may see, receive, or use subjects' information must be added. Examples:

- the research team involved in this study: Hennepin Healthcare providers, their staff, and others who may become involved in the study
- Hennepin Healthcare Research Institute and Hennepin Healthcare System, Inc.
- findings of this study may be used for scientific meetings, written reports, and publications, but no information that could be used to identify you will be disclosed for these purposes

☐ HIPAA Authorization: Does the study involve the use, collection, or disclosure of Protected Health Information?

If the research is subject to HIPAA, either use the *Hennepin Healthcare stand-alone HIPAA authorization* template to create an authorization form OR refer to it when another HIPAA authorization form is being used to ensure that the alternate form is consistent with the Hennepin Healthcare template.

☐ Compensation for Injury – Research-Related Injury Language: Is the study greater than minimal risk?

If the study involves greater than minimal risk to subjects, appropriate compensation of injury language must be included that explains what to do and who will be responsible for payment of costs associated with research-related injury. Examples:

Option 1 - Non-Sponsor Funded Compensation
If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study doctor, [name and telephone number], day or night. Medical care for any study-related sickness or injury will be available to you at Hennepin Healthcare. Financial compensation for lost wages, disability, and discomfort is not routinely available.

The cost of this medical care will be billed to you or your insurance company.

Option 2 - Sponsor Funded Compensation – Billed to Insurance
If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study doctor, [name and telephone number], day or night. Medical care for any study-related sickness or injury will be available to you at Hennepin Healthcare. Financial compensation for lost wages, disability, and discomfort is not routinely available. [The Sponsor] will pay all medical costs needed to treat any research-related injury that your insurance does not pay. [The Sponsor] will pay for this only if you have followed the directions of the study doctor. [The Sponsor] does not offer any payment other than for medical costs for the research-related injury.

Option 3 – Sponsor Funded Compensation – Not Billed to Insurance
If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study doctor, [name and telephone number], day or night. Medical care for any study-related sickness or injury will be available to you at Hennepin Healthcare. Financial compensation for lost wages, disability, and discomfort is not routinely available. [The Sponsor] will pay all medical costs needed to treat any research-related injury. [The Sponsor] will pay for this only if you have followed the directions of the study doctor. [The Sponsor] does not offer any payment other than for medical costs for the research-related injury.

Important: The Hennepin Healthcare study team is responsible for working with their HHRI grant administrator to verify that the research-related injury language in the consent(s) is consistent with the contract. Revisions to the consent form(s) may be required if there are discrepancies between the coverage described in the contract and the coverage described in the consent form(s).

If applicable to the protocol, the site-specific consent(s) must also include:

☐ Communicable Disease Reporting: Does the study involve testing for communicable diseases that require reporting to the Department of Health?

If applicable, the language in the site-specific consent(s) that describe testing for communicable diseases (e.g., hepatitis, HIV, tuberculosis) must describe the Minnesota law reporting requirements to state health authorities. Examples:

> In the event of a positive result for <insert reportable information>, reporting of the results to the Minnesota Department of Health would be necessary.
>
> **OR**
>
> If we learn about communicable, infectious, or other diseases required to be reported under Minnesota's Reportable Disease Rule, we may be required or permitted by law or policy to report this information.

☐ Mandatory Reporting: Prenatal exposure to controlled substance or excessive alcohol use during pregnancy

If the study will probe for, or is likely to elicit information about excessive alcohol or controlled substance use for nonmedical purposes during pregnancy (e.g. interviews about personal behavior including use of controlled substances or alcohol), the site-specific consent(s) must describe the following:

> If we learn about excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy, we may be required or permitted by Minnesota law or Hennepin Healthcare policy to report this information to the Hennepin County Child Protection Agency.

☐ Mandatory Reporting: Will the study probe for or likely elicit information about child or vulnerable adult abuse or neglect?

If the study will probe for, or is likely to elicit information about child or vulnerable adult abuse or neglect, the site-specific consent(s) must describe the following:

> If we learn about current or ongoing child or vulnerable adult abuse or neglect, we may be required or permitted by Minnesota law or Hennepin Healthcare policy to report this information.

☐ Compensation for Participation: Will the participants receive compensation in amount greater than $600?

If subjects may receive more than $600 in compensation, the site-specific consent(s) must include language regarding reporting information to the IRS for research payment. Example:

> If you receive a total of $600 or more in a calendar year, the IRS requires reporting of the money paid to you, and you will be responsible for reporting this on your income tax return.

☐ Radiation Risk Language: Does the study involve exposure to radiation (for research OR standard of care)?

If study procedures include exposure to radiation (e.g. x-ray, CT scan, etc.), the site-specific consent(s) must include risk language as specified by the HCMC Radiation Safety and Radioactive Materials Committee.

☐ Financial Interest: Do any Hennepin Healthcare investigators or the Hennepin Healthcare System, Inc., have a financial conflict of interest?

If applicable, investigator and/or institutional conflict of interest must be described in the site-specific consent(s) as specified by the HRRI Conflict of Interest Committee and external IRB.