HRP-831 | 3/29/2024

**WORKSHEET: Local Context Review**

The purpose of this worksheet is to provide support for IRB staff conducting a local context review for UMN study where an external IRB will conduct the IRB review. This should be conducted after “CHECKLIST: Criteria for External IRB Reliance (HRP-841)” has been completed, indicating that UMN IRB supports the reliance (see Confirm Reliance Activity in SITE Submission).

1. **Initial Review of a Request to Rely on an External IRB**

Determine that the submission qualifies for reliance on an external IRB, using HRP-841 – CHECKLIST – Criteria for Relying an External IRB. The submission must qualify before proceeding with the local context review.

1. **Local Context Review for Studies Relying on an External IRB**

**Note any missing materials, information, or ancillary reviews necessary for completing the local context review in the “Request Pre-Review Clarification” Activity:**

Overall study protocol and/or Site Supplement (HRP-508)

For protocols that request a waiver or alteration of HIPAA Authorization, the external IRB will serve as the Privacy Board.[[1]](#footnote-1)

When UMN is only a Data Coordinating Center: The submission should include information regarding the center’s standard operating procedures that address the criteria as described in Section 6 of [WORKSHEET: Criteria for Approval (HRP-314)](https://research.umn.edu/units/irb/toolkit-library/worksheets). Information should also be included in the protocol or addendum (HRP-508) submitted in ETHOS.

If the study includes adult participants that have diminished, fluctuating, or absent capacity to consent to research, the protocol/addendum complies with HRP-110 – POLICY - Capacity to Consent

The protocol complies with HRP-111 – POLICY – Research Involving Adults Under Court Jurisdiction

The protocol complies with HRP-112 – POLICY – Minnesota Laws Affecting Human Research

If the study includes non-English speaking participants, the study at a minimum complies with UMN IRB requirements described in HRP-103 – MANUAL – Investigator Manual

Description of what activities will be conducted at or by the local UMN site

External IRB of Record is appropriately selected (If selected “OTHER,” an institutional profile is required and the submission will need to be updated once available.)

Explanation as to why UMN IRB should rely on an external IRB for IRB Review that does not conflict with the Criteria for Relying on an External IRB. This information is evaluated at the time of the request to rely.

Completed Study Funding Sources page (including appropriate association of funding in ETHOS)

Study personnel have completed required IRB training (Education and Training ([HRP-066](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)))

If the overall study involves a drug or device, the relevant page(s) are completed and documentation must be provided (e.g. FDA documentation), this includes when the UMN study team will not be engaged in the drug/device aspect of the study. Regulator ancillary review is required.

Study-Related Documents page includes the following (if applicable):

Study materials that will not be altered or changed, but will be used by the site locally (e.g. surveys, questionnaires, instruments, study-wide recruitment material).

Local Site Documents page includes the following:

Informed Consent Form Draft(s) to be used locally and includes locally required language (See Section 3 for language that must be included in the consent)

Recruitment Material (if applicable) to be used locally

HIPAA Authorization Form (Standalone or Combined Consent)

If applicable, any external IRB documentation (e.g. Advarra IRB Cover Page or Local Context Review form(s))

Completed Attestation regarding PI Responsibilities when Relying on an External IRB (HRP-829)

If the local investigator holds the IND, a completed [Sponsor Investigator Responsibilities (HRP-1899)](https://research.umn.edu/units/irb/toolkit-library/templates-forms#forms) form is uploaded.

Ancillary review documentation, if applicable

All ancillary reviews are complete per HRP-309 – WORKSHEET – Ancillary Review Matrix

Fully signed reliance agreement is provided or completed through an online reliance submission system (e.g. iREX, SmartIRB)

1. **Locally Required Consent Language**

If relying on NCI CIRB, local consent language is not required at the time of local context review (unless otherwise noted).[[2]](#footnote-2)

**Access to Information.** The following text is included:

Organizations that may inspect and copy your information include the University of Minnesota Institutional Review Board (IRB) which is a committee that provides ethical and regulatory oversight of research, and other representatives of the University of Minnesota, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program (HRPP).

**Certificate of Confidentiality.** If applicable, COC language from the [UMN Consent Template](https://research.umn.edu/units/irb/toolkit-library/templates-forms#consent) is included.

**Research Related Injury.** One of the following should be included if the research involves the potential for injury.

#1 Non-sponsor funded compensation.

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

#2 Sponsor funded compensation (preferred).

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement for some medical care costs, let the study physicians know right away.

#3 Sponsor funded compensation (alternative).

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances or if you think you have suffered a research related injury, let the study physicians know right away.

**Research Participant Advocate Line.** The following text is included:

To share feedback privately with the University of Minnesota Human Research Protection Program

(HRPP) about your research experience, call the Research Participants’ Advocate Line at 612-625-

1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact

the HRPP if:

● Your questions, concerns, or complaints are not being answered by the research team.

● You cannot reach the research team.

● You want to talk to someone besides the research team.

● You have questions about your rights as a research participant.

● You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as

a research participant. You do not have to complete the survey if you do not want to. If you do choose

to complete the survey, your responses will be anonymous. If you are not asked to complete a survey,

but you would like to share feedback, please contact the study team or the University of Minnesota

HRPP.

**Protected Health Information.** One of the following is included, if applicable:

When a standalone UMN HIPAA Authorization will be used.

We are committed to respecting your privacy and keeping your personal information

confidential. When choosing to take part in this study, you are giving us permission to use

your personal health information that includes health information in your medical records

and information that can identify you. For example, personal health information may include

your name, address, phone number or social security number. Those persons who get your

health information may not be required by Federal privacy laws (such as the Privacy Rule or

what you may know as “HIPAA”) to protect it. Some of those persons may be able to share

your information with others without your separate permission. Please read the separate

HIPAA Authorization form that we have provided and discussed. The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Combined HIPAA & Consent form if External IRB is also the Privacy Board

The study doctor and study staff may share your information with representatives of the

University of Minnesota and M Health. These people may use your information to provide

oversight and administrative support for the research, conduct evaluations and reviews, and

perform other activities related to the conduct of the research.

**Mandatory Reporting.** If applicable, include one of the following Mandated or permittedReporter Language statements for studies in which researchers are probing for or likely to elicit information about drug/alcohol use during pregnancy, child or vulnerable adult abuse or neglect. In such cases, the State of Minnesota requires or permits researchers to report such information to authorities.

If we learn about current or ongoing child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or vulnerable adult] abuse or neglect.

We will not ask you about child [or vulnerable adult] abuse, but if you tell us about child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

If applicable, include language regarding the following topics in the consent form:

Communicable, infectious or other diseases required to be reported under Minnesota’s Reportable Disease Rule.

Certain wounds or conditions required to be reported under other state or federal law.

Excessive or habitual use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

**Other UMN Specific Language.** If the study involves any of the following, language from the [UMN Consent Template](https://research.umn.edu/units/irb/toolkit-library/templates-forms#consent) should be used related to the topic.

Research involving the use of the UMN Center for Magnetic Resonance Research (CMRR)

Use of the UMN Greenphire ClinCard for research participant compensation

Research involving minors (reproductive rights). NOTE: Minnesota statute provides confidentiality with respect to reproductive services for minors. The IRB understands this provision extends to pregnancy testing as part of research. Therefore, pregnancy test results may not be provided to parents/guardians or referring physicians without the consent of the minor, unless the withholding of test results would result in a potentially life-threatening health situation for that minor.

1. For reliance agreements executed under a SMART IRB Agreement or Advarra IRB, the external IRB will serve as the Privacy Board. Studies proposing to request a waiver or alteration of HIPAA authorization, must utilize an IRB that will also act as a privacy board for any reliance studies. [↑](#footnote-ref-1)
2. Consent language is agreed upon between UMN IRB and NCI CIRB and reviewed annually for studies reviewed by NCI CIRB. [↑](#footnote-ref-2)