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| 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). | |
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| 1. STUDY Submission | |
|  | The following are included in the STUDY SmartForm:  Basic Information: Overall study protocol and/or Site Supplement (HRP-508)  External IRB:  External IRB of Record is appropriately selected (If selected “OTHER” this will require the IRB staff to create an institutional profile.)  Questions 2-5 should be completed once IRB approval from the External IRB is obtained unless they already have access to the information from the Study Sponsor.  Questions 7-11 should be left unanswered until information is obtained from the External IRB regarding these regulatory determinations.  NOTE: Additional information regarding level of review, level of risk, and any regulatory determinations or waivers must be included in the external IRB approval letter.  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.  Funding page: In preparation for the ETHOS upgrade, the Funding page on both the STUDY and SITE submission must be completed.  Completed Study Scope page.  NOTE: If the overall study involves a drug or device, the relevant page should be completed, this includes when the UMN study team will not be engaged in the drug/device aspect of the study. UMN regulatory ancillary review is required.  Study-Related Documents: Any other documents should be uploaded in the SITE Submission that are UMN site specific. |
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| 1. SITE Submission | |
|  | The following are included in the SITE SmartForm:  Completed Basic Information page.  Completed Funding page.  Completed Study Team Members page. NOTE: UMN Study Personnel or Approved Personnel under an Individual Investigator Authorization Agreement listed must complete required training before allowing the PI to submit an IRB application to an external IRB.  Study personnel have completed required training (Education and Training ([HRP-066](https://drive.google.com/open?id=0B7644h9N2vLcaDF5OXljVVh3bEE)))  Completed Research Locations and Resources page.  Local Site Documents page includes the following:  Informed Consent Form Draft (See Section 3 for language that must be included in the consent)  Recruitment Material (if applicable)  If applicable, any external IRB documentation (e.g. Advarra IRB Cover Page)  Completed Attestation regarding PI Responsibilities when Relying on an External IRB (HRP-829)  If the local investigator holds the IND, a completed [IND Checklist](https://policy.umn.edu/sites/policy.umn.edu/files/forms/um1898.pdf) is uploaded.  Ancillary review documentation (see Ancillary Review Matrix (HRP-309)).  All relevant ancillary reviews have been tagged and completed per Ancillary Review Matrix (HRP-309)).  Other UMN local context requirements (if applicable):  Capacity to Consent policy ([HRP-110](https://drive.google.com/open?id=0B7644h9N2vLcR2hQaXlzbnNsUWc))  Research Involving Adults Under Court Jurisdiction ([HRP-111](https://drive.google.com/open?id=0B7644h9N2vLcTTF3dEhlMFJtQUU))  Minnesota Laws Affecting Human Research ([HRP-112](https://drive.google.com/file/d/0B7644h9N2vLcay1CVm1GblIxcms/view?usp=sharing))  Fully signed reliance agreement or SMART IRB acknowledgment (NOTE: This is uploaded and/or documented within the Pre-Review Activity by IRB staff. Must be complete prior to allowing submission to an external IRB.) |
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| 1. Required Consent Form Language.   NOTE: If relying on Advarra IRB or NCI CIRB, local consent language is not required at the time of local context review. Consent language has either been previously agreed upon per the Master Reliance Agreement (NCI CIRB) or will be reviewed by the external IRB (Advarra IRB). | |
|  | **Access to Information.**  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). |
|  | **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.**  *For studies that will* *rely on any external IRB, include the following:*  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.**  *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://drive.google.com/file/d/0B7644h9N2vLcVmwxR2dOZFRGSDg/view?usp=sharing) 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. |
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