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|  |  | FORM: UMN ADVARRA Cover Page | | | |
| Toolkit Number: HRP-823 | Version/Date: 6.0  3/28/2023 | Author:  C. Jarboe | Approved By: D. Dykhuis |
| **NOTE:** Any changes to this FORM must be approved by Advarra IRB. | | | |

**UMN ADVARRA COVER PAGE**

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| **For prompt assessment and Board review, you must include the UMN Advarra Cover Page with your initial submission to Advarra to ensure proper handling of your initial site submission.** | |
| NAME OF INSTITUTION | University of Minnesota (includes Fairview Health Services (FWA#00000325) and Gillette Children’s Specialty Healthcare (FWA #00004003)) |
| ETHOS ID # | Click or tap here to enter text. |
| PRINCIPAL INVESTIGATOR | Click or tap here to enter text. |
| PI DEPT. AFFILIATION | Click or tap here to enter text. |
| PROTOCOL NUMBER | Click or tap here to enter text. |
| STUDY TITLE | Click or tap here to enter text. |
| STUDY TYPE (Check all that apply) | UMN will be a participating site for a multi-site study  UMN will lead a multi-site study, where Advarra IRB will serve as the sIRB  UMN will conduct a single or multi-site study where an institutional conflict of interest exists  UMN will only serve as a Data Coordinating Center |
| SPONSOR NAME | Click or tap here to enter text. |
| IRB Fees:  All fees associated with the review of the study are the responsibility of the study team / sponsor. | Name Billing Point of Contact:  E-Mail Address of Billing Point of Contact:  Billing Address: |
| RELIANCE AGREEMENT | UMN-Advarra Master Agreement  SMART IRB Agreement  **NOTE:** This form should be uploaded under documents upload page, question 3/IRB Waiver of Oversight. |
| **INSTRUCTIONS FOR INVESTIGATORS:**  Use this checklist toensure that all required institutional policies, requirements, and local context considerations are included for this review. All research must be conducted in accordance with University of Minnesota (UMN) **AND** Advarra’s policies for human subjects research. Identified below are UMN specific policies that must be followed or situations in which additional UMN specific forms may be required.  **COMPLIANCE WITH UMN POLICIES****& STATE LAWS**(check all that apply)     1. **Adults with Absent, Diminished or Fluctuating Capacity to Consent ( Not Applicable)**   This study will include adults with absent, diminished or fluctuating capacity to consent. Note: Study team may not include members of this population as participants if this box is not checked. Inclusion of this population is subject to the requirements of the protocol and approval by Advarra.  If yes, check here to confirm you will comply with all applicable UMN HRP policies, checklists and guidance regarding inclusion of this population in research, including use of legally authorized representatives to consent on behalf of participants. Refer to: “POLICY: Capacity to Consent (HRP-110)”, “POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111), “SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)” and “SOP: Informed Consent Process for Research (HRP-090)”.     1. **Adults Under Court Jurisdiction ( Not Applicable)**   This study may enroll adults under court jurisdiction. This includes adults subject to a commitment hearing, under a commitment hold, classified as incompetent, or who have a court appointed guardian.  If yes, check here to confirm you will comply with all applicable UMN HRP policies, checklists and guidance regarding inclusion of this population in research. Refer to “POLICY: Minnesota Laws Affecting Human Research (HRP-112)” and “POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111).” Please indicate below the type of adult under court jurisdiction below and provide any requested additional information.    Adults under a hold. UMN policy prohibits recruiting or enolling individuals subject to a commitment petition and/or temporary voluntary confinement for any clinical drug trial or psychiatric device or biologic trial. Check here to confirm that you understand that this population may NOT be recruited or enrolled.  Adults under court appointed guardianship. UMN policy requires that a specific process be provided for enrolling adults under court appointed guardianship that will ensure all necessary judicial orders are secured. Please provide the specific process that will be followed here:  Adults classified as incompetent. UMN policy requires specific rationale be provided for including adults who are individually adjudicated or classified by law as "incompetent" and plans for use of an LAR to consent. Please provide the required specific rationale and LAR plans:   1. **Research Involving Minors ( Not Applicable)**   This study may enroll minors.  If yes, check here to confirm you will comply with all applicable UMN HRP policies, checklists and guidance regarding inclusion of this population in research. Refer to “POLICY: Minnesota Laws Affecting Human Research (HRP-112)”, “SOP: Legally Authorized Representatives, Children and Guardians (SOP-013).”   1. **Short Form Consent Process ( Not Applicable)**   If it is anticipated that individuals who speak a language other than English may be enrolled, the short form consent process should generally not be used. In this case, you must arrange for translation of the Advarra IRB-approved consent form (or request this via the sponsor).  If the study may enroll participants who were not anticipated and speak a language other than English, please check here to confirm you will **generally** comply with all applicable UMN HRP policies, checklists and guidance regarding inclusion of this population in research. Refer to “SOP: Informed Consent Process for Research (SOP-090) and “SOP: Written Documentation of Consent (SOP-091).”  **NOTE**: Advarra’s policies require specific rationale in support of the use of a short form process and prior IRB approval of all short form materials and the consent summary (often the full consent document). If a participant presents for whom the short form process is appropriate, the study team must at that time and prior to seeking consent:   * + 1. Submit a modification including the UMN Short Form (in English and the foreign language) and the Translation Certificate.     2. Obtain approval for the specific requested use and short form materials from Advarraq.     3. Use a stand-alone HIPAA authorization process (translated into the appropriate language) along with the short form.     4. Obtain a translation of the full consent document(s) and re‑consent the participant within a reasonable time frame (generally 15 days) after the use of the short form.  1. **Conflict of Interest (COI) ( Not Applicable)**   A study team member involved in this research has disclosed potential conflict of interest per UMN definitions.  If yes, check here to confirm that the potential COI was reviewed by the UMN’s COI Program; and that the COI Program’s determination or Conflict of Interest Management Plan (CMP) is included in this IRB submission. (Note: Advarra IRB may impose a more restrictive CMP if deemed necessary to protect participants.)  The University of Minnesota has an institutional financial conflict of interest per UMN definitions.  If yes, check here to confirm that the potential COI was reviewed by the UMN’s COI Program; and the COI Program’s determination or Conflict of Interest Management Plan (CMP) is included in this IRB submission. (Note: Advarra IRB may impose a more restrictive CMP if deemed necessary to protect participants.)  **INFORMED CONSENT & HIPAA REQUIREMENTS** (check all that apply, including options as applicable):   1. **Screening, Recruiting, or Determining Eligibility ( Not Applicable)**   The study will seek to collect private information directly from prospective participants for the purpose of screening, recruiting, or determining eligibility prior to obtaining informed consent for the study and will require an informed consent script for this purpose.   1. **HIPAA Privacy Authorization -** Select only one:   This study will use the **embedded** HIPAA authorization language in the informed consent(s). If embedded authorization used, must include language that allows sharing with the University of Minnesota and M Health for those who provide support for the research or who have authority to oversee research. (**Note:** Option to embed the HIPAA authorization is not available to Gillette).  This study will use the University of Minnesota **stand-alone** HIPAA Privacy Authorization. A copy of the HIPAA Authorization is attached. This authorization has been reviewed and approved by the University of Minnesota Health Information Privacy & Compliance Office (HIPCO). Advarra will not review this document, and will remove any HIPAA that was blended into the sponsor-level consent form.  This study will use the University of Minnesota **combined** HIPAA Privacy Authorization and informed consent form.  HIPAA Authorization is not necessary (this study is requesting a **waiver** of HIPAA Authorization or protected health information is not being used or collected).   1. **Research Related Injury and Informed Consent ( Not Applicable)**   Statements about who will provide care for research related injury and who is responsible for paying for must be consistent between the clinical trial agreement and informed consent form. If the research involves the potential for injury, Advarra will add UMN’s appropriate language regarding appropriate compensation for injury based on who is paying for any injuries/illnesses.  Select only one:  Sponsor not paying for injuries/illnesses (*Option 1 on the UMN Informed Consent Boilerplate Language*)  Sponsor paying for injuries/illnesses (*Option 2 on the UMN Informed Consent Boilerplate Language*)  If the preferred UMN injury compensation language is unacceptable to the study sponsor and they state their objection in writing, the UMN alternative language may be used. (*Option 3 on the UMN Informed Consent Boilerplate Language*)  The Secretary issued a Public Readiness and Emergency Preparedness (PREP) Act declaration for COVID-19 countermeasures on March 10. Essentially, this action restricts participants’ ability to sue related to “countermeasures” described in the declaration. In response to the PREP Act, the IRB requires the following language be added to all consent forms for research that involves use of a drug, biologic material, or device to diagnose, mitigate, prevent, treat, cure, or limit harm related to COVID-19:  *Due to the coronavirus public health crisis, the federal government has issued an order that may limit your ability to recover damages if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your ability to recover damages from the University, researchers, healthcare providers, study sponsor, manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death due to this study. To find out more about this “Countermeasures Injury Compensation Program” go to*  [*https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427*](https://www.hrsa.gov/cicp/about/index.html%C2%A0or%20call%201-855-266-2427)*.*   1. **Mandatory Reporting and Informed Consent ( Not Applicable)**   If applicable, Advarra will include one of the following Mandated or permitted Reporter Language statements for studies in which researchers are probing for or likely to elicit information about child or vulnerable adult abuse or neglect. In such cases, the State of Minnesota requires or permits researchers to report such information to authorities. This language would be included in the “What happens to the information collected for the research” or comparable section.  Select only one:  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 abuse child [or vulnerable adult], 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.   1. **Research Involving Use of the University of Minnesota Center for Magnetic Resonance Research (CMRR) ( Not Applicable)**   My research involves the use of the University of Minnesota Center for Magnetic Resonance Research (CMRR). I tracked in the applicable language to the **sections** of the consent form as provided by the [CMRR template language](https://research.umn.edu/units/irb/toolkit-library/templates) found in HRPP-592 and provided the rationale for this change (i.e. comment of the tracked informed consent or cover letter):       . Note: If Advarra is already the IRB of record, you must first obtain the Advarra-approved consent form into which you will track this language.   1. **Female Minors and Pregnancy Testing ( Not Applicable)**   My research includes pregnancy tests for female minors   1. **Participant Compensation ( Not Applicable)**   Participants may receive over $600 in a single calendar year. Advarra will include UMN language to address federal tax law reporting requirements.  The study will utilize Greenphire ClinCard for compensating participants.  The study is using appointment reminders and/or payment reminders of updates via text message or email via Greenphire.   1. **Ancillary reviewer required consent language ( Not Applicable)**   My research requires additional changes to the informed consent by other ancillary  reviewers/committees (e.g. Fairview Health Services, radiation safety). I tracked in the applicable  language to the sections of the consent form and provided the rationale for this change (i.e., comment  on the tracked informed consent or cover letter):  Note: If Advarra is already the IRB of record (cIRB), you must first obtain the Advarra-approved consent form into which you will track this language.   1. **Communicable Disease Reporting and Informed Consent ( Not Applicable)**   My research includes communicable disease reporting. Advarra will include UMN language to address.  **16. Participant Costs for Research Participation ( Not Applicable)**  My research requires additional language to the participant costs for research participation section of the informed consent. I tracked in the applicable language to the sections of the consent form and provided the rationale for this change (i.e., comment on the tracked informed consent or cover letter):  Note: If Advarra is already the IRB of record (cIRB), you must first obtain the Advarra-approved consent form into which you will track this language.  **PRINCIPAL INVESTIGATOR’S ASSURANCE**  As Principal Investigator for this study with my submission I certify the following:   * I am aware of and will comply with both Advarra and applicable University of Minnesota policies for human subjects research. * I am not currently nor will I begin conducting the referenced clinical trial before formal Advarra IRB approval is granted **and** a clinical trial agreement is fully executed.  Principal Investigator Signature Date **UNIVERSITY OF MINNESOTA HUMAN RESEARCH PROTECTION PROGRAM OFFICE ASSURANCE**  The request for reliance on Advarra IRB for the above referenced study has been reviewed and approval to pursue IRB review by Advarra is granted. HRPP Signature Date | |
| **THIS SECTION DESCRIBES CURRENT HANDLING REQUIREMENTS FOR THE INSTITUTION ABOVE AND IS FOR ADVARRA USE ONLY**  Please see the Account Special Handling Document (ASHD) attached to the account record of University of Minnesota | |