**INSTRUCTIONS:**

* *Use this LOCAL PROTOCOL ADDENDUM TEMPLATE (HRP-508) to prepare a document that provides NU site-specific information only.*
* *If a section is not applicable to your research, delete the instructions and mark “NA” or delete the section.*
* *Upload the sponsor’s protocol and the local protocol addendum in the protocol section of the application in eIRB+.*
* *As you are composing the Local Protocol Addendum,* ***delete all instructions in italics, including these,*** *so that no instructions are contained in the final version of your document.*

**PROTOCOL TITLE:** *(Include the full protocol title.*)

**PRINCIPAL INVESTIGATOR**:

*Name*

*P.I. Department sponsoring/supporting the study*

*Telephone Number*

*Email Address*

**VERSION DATE**: (*Include the version date of this site supplement.)*

**FEDERAL FUNDING:**

*(Complete the following matrix if this study will be supported by federal funds. Add additional matrices for each unique funding source. Remove this section if the study will not be supported by federal funds. Reminder: This information must match the information you provide on the funding page of the eIRB+ application.)*

|  |  |  |
| --- | --- | --- |
| Funding Agency: |  | |
| Sponsored Research ID#: |  | |
| Does the grant indicate that covered activities will include Human Research?  (Yes / No / Unknown) |  | |
|  | Institution Name: | [Human Research Assessment](https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html) \*\*\*  (e.g., Non-Exempt Human Research, Exempt Human Research, Not Human Research, etc.) |
| Prime Award Recipient\* |  |  |
| Sub-Award Recipients\*\* |  |  |
|  |  |  |
|  |  |  |

\* The prime award recipient is always engaged in Human Research and must have IRB oversight when one or more sub-award recipients conduct non-exempt Human Research.

*Many federal agencies require that when more than one domestic site engages in non-exempt Human Research, all sites must rely on the review of one “Single IRB.” If this applies to your study, you must obtain a Single IRB Letter of Support and IRB Fee Quote from the Northwestern University IRB Office before the Northwestern University IRB will review your study. Submit a* [*Single IRB Consultation Request*](https://irb.northwestern.edu/reliance/single-irb-planning.html) *to initiate this process.*

*\*\*Include the activities of all non-Northwestern affiliated sites in the multi-site/collaborative research section of the protocol below.*

*\*\*\*The federal funding application should include plans for whether award recipients will engage in Human Research. Based on the funding application, provide an assessment of the activities at each site and update the table if the planned activities change or if another IRB reviews the activities and makes a different determination.*

**Inclusion and Exclusion Criteria**: (*Describe any inclusion or exclusion criteria that will differ for your local site compared to the sponsor’s protocol. For example, if the sponsor’s protocol allows the enrollment of children, but you will not enroll children at NU, indicate that here.)*

**PROTOCOL PROCEDURES:** *(Describe any procedures that will differ for this site compared to the sponsor’s protocol. For example, if NU will not be participating in the biomarker sub-study. Also this section should be used to indicate all procedures that are standard of care, such as imaging. This includes the frequency and/or number of standard of care procedures)*

**Withdrawal of Participants**: (*Describe procedures that will be followed locally, if different from the sponsor’s protocol, when participants withdraw from the research*.)

**Vulnerable Populations**: (*If the research involves individuals who are vulnerable to coercion or undue influence, describe any additional, site-specific safeguards included to protect their rights and welfare*.)

(*Review any applicable* [*checklists*](https://irb.northwestern.edu/resources-guidance/checklists-worksheets/index.html#tab-panel1) *to ensure sufficient information is provided for review.*

* *HRP-412 CHECKLIST: Pregnant Women*
* *HRP-413 CHECKLIST: Neonates*
* *HRP-414 CHECKLIST: Neonates of Uncertain Viability*
* *HRP-415 CHECKLIST: Prisoners*
* *HRP-416 CHECKLIST: Children (defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research)*
* *HRP-417 CHECKLIST: Adults with Impaired Decision-making Capacity)*

**Sharing of Results with Participants:** (*Describe if and how study results or individual participant results [such as results of investigational diagnostic tests, genetic tests, or incidental findings] will be shared with the participants or others (e.g., the participant’s primary care physicians).*

**Setting:** (*Describe the NU sites or locations where your research team will conduct the research. Include:*

* *where research procedures will be performed.*
* *describe the composition and involvement of any community advisory board.*
* *For research conducted outside of the organization and its affiliates describe:*
  + *Site-specific regulations or customs affecting the research for research outside the institution.*
  + *Local scientific and ethical review structure outside the institution*.)

**Resources Available:** (*Describe other resources available to conduct the research: For example, as appropriate:*

* *Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research. You do not need to list individual names of your staff in this protocol.*
* *Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to for recruitment? What percentage of those potential participants do you need to recruit?*
* *Describe the availability of medical or psychological resources that participants might need because of any anticipated consequences of the human research.*
* *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions*.)

**Prior Approvals:** (*Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety approval.*)

**Local Recruitment Methods:** (This section is for recruitment methods under the control of the local site and not central recruitment managed by the sponsor. Your recruitment plan should incorporate methods that specifically address, and detail how potential participants from particular racial and ethnic groups/under-represented populations (with respect to the study) will be recruited. This is to ensure that the recruitment plan is inclusive and representative of the eligible population within the location at which the research is being conducted, and considers the impact of the research on all such populations.

* *Describe when, where, and how potential participants will be recruited.*
* *Describe the source of participants.*
* *Describe the methods that will be used to identify potential participants.*
* *Describe materials that will be used to recruit participants. Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for local broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
* *Describe the amount and timing of any payments to participants*.)

**Local Number of Participants:** (*Indicate the total number of participants to be accrued locally. Distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures*.)

**Data, specimen banking and Confidentiality:** (*Describe the local procedures for maintenance of confidentiality.*

* *Where and how will data or specimens be stored locally?*
* *How long will the data or specimens be stored locally?*
* *Who will have access to the data or specimens locally?*
* *Who is responsible for receipt or transmission of the data or specimens locally?*
* *How will data and specimens be transported locally?*)

**Provisions to Protect the Privacy Interests of Participants:** (*Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.)*

*(Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.)*

*(Indicate how the research team is permitted to access any sources of information about the participants.)*

**Data and Specimen Banking**: *(The sponsor’s protocol may require banking data or specimens for future use and both storage and use will be determined by the sponsor. If additional data or specimens will be banked locally for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.)*

*(List the data to be stored or associated with each specimen banked locally.)*

(*Describe the procedures to release locally banked data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens*.)

**Compensation for Research-Related Injury:** (*If the research involves more than Minimal Risk to participants, describe the available compensation in the event of research related injury. Provide a copy of contract language, if any, relevant to compensation for research-related injury.)*

**Economic Burden to Participants:** (*Describe any costs that participants may be responsible for because of participation in the research, e.g., fuel, parking, childcare*.)

**Consent Process:** (*Indicate if you will you be obtaining consent; and if so, describe the following:*

* *Where the consent process takes place.*
* *Any waiting period available between informing the prospective participant and obtaining the consent.*
* *Any process to ensure ongoing consent.*
* *The role of the individuals listed in the application as being involved in the consent process.*
* *The time that will be devoted to the consent discussion.*
* *Steps that will be taken to minimize the possibility of coercion or undue influence.*
* *Steps that will be taken to ensure the participants’ understanding.*
* *\*Refer to Standard Operating Procedures for Informed Consent Process for Research (HRP-090))*

(*Provide an explanation for any requirement(s) for obtaining consent that cannot be met*.)

**Non-English Speaking Participants:** (*If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in the participants’ preferred language. Indicate the language that will be used by those obtaining consent and by those communicating any relevant future information*.)

**Waiver or Alteration of Consent Process:** (*If consent will not be obtained, required information will not be disclosed, or the research involves deception, review the CHECKLIST: Waiver or Alteration of Consent Process (HRP-410) to ensure you have provided sufficient information for the IRB to make these determinations*.)

(*If the research involves a waiver of the consent process for planned emergency research, review the CHECKLIST: Waiver of Consent for Emergency Research (HRP-419) to ensure you have provided sufficient information for the IRB to make these determinations*.)

**Participants who are not yet adults**: (*Describe the criteria that will be used to determine if a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years*.)

*(For research conducted in Illinois, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in Illinois meet the definition of “children.”)*

*(For research conducted outside of Illinois, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”)*

*(Describe if parental permission will be obtained from:*

*Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*

*Or*

*One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.)*

*(Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.)*

*(Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.)*

*(When assent of children is obtained, describe how it will be documented. The IRB allows for documentation of assent directly in the consent document. The IRB does not routinely require separate assent documents and does not routinely require children to sign assent documents. However, those options are available in the template consent document referenced in the section below.)*

**Adults WITH IMPAIRED DECISION-MAKING CAPACITY:**  (*Describe the process to determine if an individual is capable of consent. The IRB allows for documentation of assent directly in the consent document. The IRB does not routinely require separate assent documents and does not routinely require adults with impaired decision-making capacity to sign assent documents. However, those options are available in the template consent document referenced in the section below.)*

**Adults Unable to Consent:** (*List the individuals from whom permission will be obtained in order of priority. (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child*.

* + *For research conducted in Illinois, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in Illinois meet the definition of “legally authorized representative.”*
  + *For research conducted outside of Illinois, describe which individuals are authorized under applicable law to consent on behalf of a prospective participant to his or her participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”*
  + *Describe the process for assent of the participants. Indicate if:*
    - *Assent will be required of all, some, or none of the participants.* 
      * *If some, indicate which participants will be required to assent and which will not.*
      * *If assent will not be obtained from some or all participants, provide an explanation of why not.*
    - *Describe if assent of the participants will be documented and define the process to document assent. The IRB allows for documentation of assent directly in the consent document. The IRB does not routinely require separate assent documents and does not routinely require participants to sign assent documents. However, those options are available in the template consent document referenced in the section below.*
  + *Describe the process for obtaining consent from participants who were previously unable to consent for themselves.)*

**Process to Document Consent in Writing:** (*Describe if and how consent of the participant will be documented in writing*.)

# Study Intervention/Investigational Agent:

# *(If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.)*

# *(If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.)*

# *(All research protocols involving investigational drugs at NMH must utilize the IDS Pharmacy for the storage, dispensing, and control of the investigational drug, whether for inpatient or outpatient use. For more information about the IDS Pharmacy, visit their dedicated* [*website*](https://nmhealth.sharepoint.com/sites/nmh-pharrm/SitePages/nmh-pharm/nmh-pharm-clinical-care/nmh-pharm-ids.aspx) *(must be logged into NMI to access) or email them at* [*nminvestigationaldrugservice@nm.org*](mailto:nminvestigationaldrugservice@nm.org)*)*

# *(If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:)*

* + - Identify the holder of the IND/IDE/Abbreviated IDE.
    - Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

|  |  |  |  |
| --- | --- | --- | --- |
| ***Applicable to:*** | | | |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

**MULTI-SITE OR COLLABORATIVE RESEarcH:**

*Multi-site and collaborative research occurs when researchers from NU and external institutions, or individual external investigators, are involved in carrying out the research. Provide the following information:*

* *Which institutions or individuals are participating in the research?*
* *What activities will institutions or individuals participate in?*
* *Will each institution or individual’s IRB review their own activities or will one IRB serve as the IRB of Record?*

*Regardless if you are unsure how to pursue IRB review and oversight for your multi-site or collaborative research, please indicate your compliance with the following statements:*

* *No activities will occur at external sites until local IRB review is pursued or reliance agreements are fully executed.*
* *Any external site sign-offs or permissions will be acquired by external study teams in accordance with their local policies.*
* *IRB approval letters from external sites, documentation that IRB review at external sites is unnecessary, or fully executed reliance agreements will be provided when available with accompanying protocol updates.*
* *Non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

*If one IRB will serve as the IRB of Record for all institutions or individuals engaged in the study, also known as reliance, please provide a detailed reliance plan:*

* *Is reliance mandated per federal guidelines or sponsor requirement?*
* *If this research is federally funded, who is the prime awardee?*
* *Who is the proposed IRB of Record for all participating sites?*
* *What type of reliance agreement will be utilized?*
* *When will institutions or individuals be onboarded? When NU is the proposed IRB of Record, we prefer to pursue review of the NU site and overall study scope first, and onboard institutions or individuals in subsequent modifications via fully executed reliance agreements. Onboarding during the initial review process may delay initial approval.*
* *How will modifications to study procedures be communicated to institutions or individuals, and approved prior to implementation? How will participating institutions or individuals be kept abreast of any problems, interim results, or the eventual closure of the study? See WORKSHEET: Communication and Responsibilities (HRP-830).*
* *How will information be managed to ensure protection of participants? All institutions and individuals must safeguard data, including secure transmission of data, as required by applicable local information security policies, state laws, and federal regulations.*

*Reliance agreements are formal arrangements between institutions allowing an IRB, institution, or individual to rely on the IRB of another institution for review of human research. The NU IRB will not serve as IRB of record for another IRB, institution, or individual unless they have agreed to this arrangement. Please see our website for further information:* [*https://irb.northwestern.edu/reliance/*](https://irb.northwestern.edu/reliance/)

*If your research involves non-exempt, federally funded, human research, happening at multiple research sites you may be required to establish a Single IRB via reliance agreements. When NU serves as the Single IRB fees may be applicable. Please see our website for further information:* [*https://www.irb.northwestern.edu/single-irb/*](https://www.irb.northwestern.edu/single-irb/)

*The NU IRB has agreements in place to serve as the IRB of record and HIPAA Privacy Board for* ***Northwestern Memorial Healthcare (NMHC), Northwestern Medicine affiliated institutions, and Shirley Ryan AbilityLab****. If your research involves collaborations with these institutions, and a Northwestern faculty member, you do* ***NOT*** *need to fill out this section of the protocol.*