**NON-CLINICAL PROTOCOL TEMPLATE**

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER:**

**DATE:**

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# Objectives

* 1. Describe the purpose, specific aims, or objectives.
  2. State the hypotheses to be tested.

# Background

* 1. Describe the relevant prior experience and gaps in current knowledge.
  2. Describe any relevant preliminary data.
  3. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

# Multi-Site Research

* 1. If you would like to use NJH IRB as the singleIRB for this protocol, please contact NJH HRPP office for pre-approval.
  2. If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:
     + All sites have the most current version of the protocol, consent document, and HIPAA authorization.
     + All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site’s IRB of record).
     + All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
     + All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
     + All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
     + All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.
  3. Describe the method for communicating to engaged participating sites:
     + Problems (inclusive of reportable events).
     + Interim results.
     + The closure of a study
  4. If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.
     + Where and how data or specimens will be stored locally?
     + How long the data or specimens will 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 data and specimens will be transported locally?

# Study Timelines

* 1. Describe:
     + The duration of an individual subject’s participation in the study.
     + The duration anticipated to enroll all study subjects.
     + The estimated date for the investigators to complete this study (complete primary analyses)

# Study Endpoints

* 1. Describe the primary and secondary study endpoints.
  2. Describe any primary or secondary safety endpoints.

# Inclusion and Exclusion Criteria

* 1. Describe how individuals will be screened for eligibility.
  2. Describe the criteria that define who will be included or excluded in your final study sample.
  3. Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)
     + Adults unable to consent
     + Children
     + Pregnant women
     + Prisoners

# Number of Subjects

* 1. Indicate the total number of subjects to be accrued locally.
  2. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)
  3. If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

# Procedures Involved

* 1. Describe and explain the study design.
  2. Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.
  3. Describe:
     + Procedures performed to lessen the probability or magnitude of risks.
     + Attach all subject-facing material such as questionnaires and/or diary cards
  4. What data will be collected including long-term follow-up.

# Data and Specimen Banking

* 1. If data or specimens will be banked 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.
  2. List the data to be stored or associated with each specimen.
  3. Describe the procedures to release 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.

# Data Management and Confidentiality

* 1. Describe the data analysis plan, including any statistical procedures.
  2. Provide a power analysis.
  3. Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.
  4. Describe any procedures that will be used for quality control of collected data.
  5. Describe how data or specimens will be handled study-wide:
     + What information will be included in that data or associated with the specimens?
     + Where and how data or specimens will be stored?
     + How long the data or specimens will be stored?
     + Who will have access to the data or specimens?
     + Who is responsible for receipt or transmission of the data or specimens?
     + How data or specimens will be transported?

# Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects.

* 1. Describe:
     + The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
     + What data are reviewed, including safety data, untoward events, and efficacy data.
     + How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
     + The frequency of data collection, including when safety data collection starts.
     + Who will review the data.
     + The frequency or periodicity of review of cumulative data.
     + The statistical tests for analyzing the safety data to determine whether harm is occurring.
     + Any conditions that trigger an immediate suspension of the research.

# Withdrawal of Subjects

* 1. Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.
  2. Describe any procedures for orderly termination.
  3. Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

# Risks to Subjects

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Please list risks procedure by procedure. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.
  2. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
  3. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
  4. If applicable, describe risks to others who are not subjects.

# Potential Benefits to Subjects

* 1. Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.
  2. Indicate if there is no direct benefit. Do not include benefits to society or others.

# Vulnerable Populations

* 1. If the research involves individuals who are pregnant or vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.
     + Pregnant Women
     + Children.
     + Prisoners
     + Cognitively Impaired Adults

# Community-Based Participatory Research

* 1. Describe involvement of the community in the design and conduct of the research.

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

# Sharing of Results with Subjects

* 1. Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how the results will be shared.

# Setting

* 1. Describe the sites or locations where your research team will conduct the research.
     + Identify where your research team will identify and recruit potential subjects.
     + Identify 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 organization.
       - Local scientific and ethical review structure outside the organization.

# Resources Available

* 1. Describe the qualifications (e.g., CITI 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.
  2. Describe other resources available to conduct the research: For example, as appropriate:
     + Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
     + Describe the time that you will devote to conducting and completing the research.
     + Describe your facilities.
     + Describe the availability of medical or psychological resources that subjects might need as a result of an 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

* 1. 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.)

# Recruitment Methods

* 1. Describe the source of subjects.
  2. Describe when, where, and how potential subjects will be recruited.
  3. Describe the methods that will be used to identify potential subjects.
  4. Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application.)

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

* 1. Describe the methods that will be used to identify potential subjects.
  2. Describe when, where, and how potential subjects will be recruited.
  3. Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application.)

# Provisions to Protect the Privacy Interests of Subjects

* 1. Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.
  2. Describe what steps you will take to make the subjects 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 subject might experience in response to questions, examinations, and procedures.
  3. Indicate how the research team is permitted to access any sources of information about the subjects.

# Economic Burden to Subjects

* 1. Describe any costs that subjects may be responsible for because of participation in the research.

# Consent Process

* 1. Indicate whether you will you be obtaining consent, and if so describe:
     + Where will the consent process take place
     + Any waiting period available between informing the prospective subject and obtaining the consent.
     + Any process to ensure ongoing consent.
     + Whether you will be following “SOP: Informed Consent Process (CON-100).” If not, describe:
       - 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 subjects’ understanding.

**Non-English Speaking Subjects**

* + - Indicate what language(s) other than English are understood by prospective subjects or representatives.
    - If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* + - Please see NJH HRPP SOP Sections 15.10, 15.11 and 15.12

**Children**

* + - Please see NJH HRPP SOP Section 16.6
* Describe the criteria that will be used to determine whether a prospective subject 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.)
  + - Describe whether 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.
      * 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 whether and how it will be documented.

**Cognitively Impaired Adults**

* + - Please see NJH HRPP SOP Section 16.7
    - Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.

**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 the state, review “Policy: Legally Authorized Representatives” to be aware of which individuals in the state meet the definition of “legally authorized representative.”
      * For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their 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 “Policy: Legally Authorized Representatives”
    - Describe the process for assent of the subjects. Indicate whether:
      * Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
      * If assent will not be obtained from some or all subjects, an explanation of why not.
      * Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.