INSTRUCTIONS:

* You may use this document as a guide to write a protocol.
* You may deviate from the suggested inclusionary elements provided in this document. You may use a different format, order, outline or template provided the necessary information is included.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, remove the sections as appropriate.
* If you use this template, delete the instructions (the sections in RED).
* If you already have a protocol:
  + Review this document to ensure that your protocol addresses the relevant information and add missing information.
  + If you cannot add missing information to the protocol, provide the information in a separate document.
  + Do not duplicate information already present in the protocol.

1. Abstract of the study

Provide a summary of the study (recommended length: 250 words).

include:.

1) overview of study design

2) population of interest

3) aim of research

4) experimental design of the study

1. Protocol Title

Include the full protocol title as listed on the Application for Human Research.

1. Sponsor / Funding

If the research is funded or sponsored, name the organization that is funding or sponsoring the research.

If Temple is a sub-awardee, indicate both the originating funder (e.g., NIH) and the direct recipient (i.e., the organization providing Temple with the funding).

1. IRB Review History

If you have submitted this protocol for review by an external IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information.

1. Investigator

Include the principal investigator’s name as listed on the Application for Human Research.

1. Objectives

Describe the purpose, specific aims, or objectives.

State the hypotheses to be tested.

1. Background

Describe the relevant prior experience and gaps in current knowledge.

Describe any relevant preliminary data.

Provide the scientific or scholarly background, rationale, and significance of the Human Research based on the existing literature and how will it add to existing knowledge.

1. Setting of the Human Research

Describe the sites at which your research team will conduct the research. If applicable, describe:

* Identify the site(s) where your research team will identify and recruit potential subjects.
* Identify the site(s) where your research procedures will be performed.
* Composition and involvement of any community advisory board.
* For research outside of the organization and its affiliates:
  + Site-specific regulations or customs affecting the research for research outside the organization.
  + Local scientific and ethical review structure outside the organization.

1. Resources Available to Conduct the Human Research

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 trial within the agreed trial period.

Describe the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.

Describe your facilities.

Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the Human Research.

Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

1. 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.)

1. Study Design
   1. Recruitment Methods

Describe the source of subjects.

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. Include copies of these documents with the application. For advertisements, submit the final copy of printed advertisements. When advertisements are taped for broadcast, provide 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.

* 1. Inclusion and Exclusion Criteria

Describe how you will screen for eligibility.

If applicable: Describe what will occur with screen failures (those participants that do not meet inclusion criteria) and with the information/materials collected during screening.

Describe the criteria that define who will be included or excluded in your final study sample.

Indicate specifically whether you will include or exclude each of the following special populations:

• Adults unable to consent

• Individuals who are not yet adults (infants, children, teenagers)

• Pregnant women

• Prisoners

• Individuals who do not understand English

* 1. Local Number of Subjects

Indicate the total number of subjects to be accrued locally.

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.)

* 1. Study-Wide Number of Subjects

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

* 1. Study Timelines

Describe (in relation to IRB approval, not specific dates):

* The duration of a 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)
  1. Study Endpoints

Describe the primary and secondary study endpoints. This is also called the primary outcome parameter. It is defined as the specific parameter or observation used to measure the effect of the intervention of interest. For example, a study may be conducted until the reoccurrence of disease, or change in blood pressure, or differences in proportions. Note that primary or secondary endpoints are not limited to clinical trials.

Describe any primary or secondary safety endpoints. Examples may include evidence of liver toxicity, an inability to tolerate further chemotherapy, or other side effects.

* 1. Procedures Involved in the Human Research

Describe the study procedures and how the data will be analyzed.

**For retrospective studies:**

Specify the exact date range over which medical charts will be selected. Example: January 1, 2012- December 31, 2015.

For retrospective chart reviews, all of the specific data elements should be described in the protocol or on the data collection form that will be used to facilitate data extraction from the medical record.

**For prospective studies:**

Describe the study procedures.

Provide a detailed description of the behavioral and social intervention(s)/interactions and/or surgical or other medical procedural intervention(s) included in this study. If one or more intervention(s) will be compared to a control intervention or to treatment as usual, include a general description of these.

Provide a schedule of procedures being performed, including procedures being performed for screening (e.g., Randomization) and/or being performed to monitor subjects for safety or minimize risks.

Include information about who will administer the intervention/interaction and how the intervention/interaction will be performed. In addition, describe the schedule of the intervention procedure(s), including the number of interventions/interactions, frequency, and the approximate duration.

Describe procedures taken to lessen the probability or magnitude of risks.

Identify which procedures/lab evaluations are being done as part of the Human Research and which are being conducted anyway for other reasons (standard of care).

**Describe all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.**

Describe the source records that will be used to collect data about subjects. Attach all surveys, scripts, and data collection forms.

Describe the data that will be collected, including long-term follow-up.

* 1. Data and Specimen Banking

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.

List the data to be stored or associated with each specimen.

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.

* 1. Data Management

Describe the data analysis plan, including any statistical procedures.

Provide a power analysis.

Describe the steps that will be taken to 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.

Describe any procedures that will be used for quality control of collected data.

Describe how data and 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 and specimens will be transported?
  1. Provisions to Monitor the Data to Ensure the Safety of subjects

This section is required when Human Research involves more than minimal risk to subjects.

Describe the plans to periodically evaluate the data collected regarding harms and benefits to determine whether subjects remain safe.

Describe who will review the data.

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Describe when (the frequency of) data are reviewed.

Describe any stopping criteria.

* 1. Withdrawal of Subjects

Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

1. Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects’ participation in the research. Include the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus if the subject is or becomes pregnant.

If applicable, describe risks to others who are not subjects.

1. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit. Do not include benefits to society or others.

1. Privacy and Confidentiality

Describe whether the study will use or disclose subjects’ Protected Health Information (PHI).

If the study uses or discloses PHI, the PI must do one of the following:

Submit a “HIPAA Authorization English (HRP-505)” or justify a waiver of HIPAA authorization.

The criteria for a waiver of HIPAA authorization can be found in the “WORKSHEET: HIPAA Waiver of Authorization (HRP-428).”

Additional information regarding PHI and HIPAA can be found in the “FAQ” section of the Temple IRB website.

Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, Certificates of Confidentiality, and separation of identifiers and data).

If any of the data is subject to HIPAA regulations, ensure that said data are stored in a HIPAA-compliant manner (e.g., paper records stored behind two locks and electronic data stored in a password-protected and encrypted manner).

Describe whether results (study results or individual subject results, such as results of genetic tests or incidental findings) will be shared with subjects or others (e.g., the subject’s professor, teacher, advisor, counselor, or primary care physician) and if so, describe how it will be shared.

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 with or whom they provide personal information to.

Describe the steps that 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.

Indicate how the research team is permitted to access any sources of information about the subjects.

If the NIH has issued a Certificate of Confidentiality for this research, indicate as such.

1. Compensation for Research-Related Injury

If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury.

Provide a copy of contract language, if any, (e.g., clinical trial agreement) relevant to compensation for research-related injury.

1. Economic Burden to Subjects

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

1. Subject Compensation

Describe the amount and timing of any payments to subjects. Indicate if payments will be in the form of a gift card.

Describe what information will be collected from subjects for the purposes of PI reimbursement.

1. Consent Process

* Indicate whether you will follow “INVESTIGATOR GUIDANCE: Informed Consent (HRP-802).”
* If not, provide a description of your consent process including:
  + - 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.
    - 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 the language(s), other than English, that 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.

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

* Review the “CHECKLIST: Waiver of Consent (HRP-300)” to ensure you have provided sufficient information for the IRB to make these determinations.
* If the Human Research involves a waiver of the consent process for planned emergency research, please review the “CHECKLIST: Waiver of Consent HHS (HRP-300)” to ensure you have provided sufficient information for the IRB to make this determination.
* If the Human Research involves a waiver of the consent process that includes use or disclosure of protected health information (PHI), please review the “WORKSHEET: HIPAA Waiver of Authorization (HRP-428)” to ensure that you have provided sufficient information for the IRB to make these determinations.

**Subjects who are not yet adults (infants, children, teenagers)**

* For research conducted in the state of Pennsylvania, indicate that you will follow “POLICY: Legally Authorized Representatives Children and Guardians (HRP-021)”
* For research conducted out of the state of Pennsylvania, list the individuals from whom permission will be legally obtained according to the state where the research is being conducted.
* 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 require assent.
* When assent of children is obtained, describe whether and how it will be documented.

**Cognitively Impaired Adults**

* Describe the process to determine whether an individual is capable of consent.

**Adults Unable to Consent**

* For research conducted in the state, indicate you will follow “POLICY: Legally Authorized Representatives Children and Guardians (HRP-021)”
* For research conducted out of the state 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.)
* Describe the process for assent of the subjects. Indicate whether:
  + Assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.
  + If assent will not be obtained from some or all subjects, submit an explanation.
  + Describe whether assent of the subjects will be documented and the process to document assent.

1. Process to Document Consent in Writing

Indicate whether you will follow “INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803).” If not, provide a description of how you will document consent in writing.

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

Review “CHECKLIST: Waiver of Documentation of Consent (HRP-303)” to ensure that you have provided sufficient information to allow the IRB to waive written documentation of consent.

1. Vulnerable Populations

If the Human Research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards to protect their rights and welfare.

Indicate whether you will include any of the following populations:

* Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Review the following documents as applicable to ensure you have provided sufficient information for the IRB allow inclusion of specific vulnerable populations:
* CHECKLIST: Pregnant Women (HRP-305)
* CHECKLIST: Neonates of Uncertain Viability (HRP-306)
* CHECKLIST: Nonviable Neonates (HRP-307)
* CHECKLIST: Prisoners (HRP-308)
* CHECKLIST: Children (HRP-310)
* CHECKLIST: Wards (HRP-311)
* WORKSHEET: Adults Lacking Capacity (HRP-414)

1. Drugs or Devices

If the research involves drugs or devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA.

If the research involves drugs or devices, 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 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 FDA sponsor requirements 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 |  |

1. Multi-Site Human Research

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 if applicable, HIPAA authorization.
* All required approvals 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 as required by local information security policies.
* All local site investigators conduct the study appropriately.
* All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.

Describe the method for communicating to engaged participating sites:

* Problems.
* Interim results.
* The closure of a study

1. Sharing of Results or Incidental Findings with Subjects

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 it will be shared.

If the Human Research involves genomic and other laboratory testing and/or imaging procedures, then the protocol must include the 4 elements listed below as applicable.

Indicate if this section is applicable to the Human Research and provide the appropriate information under each heading.

1. A statement on whether or not radiologic procedures conducted as part of the research will be of clinical quality.
2. A statement that speaks to the whether a subject’s cellular material will be used for current and/or potential future genomic testing or biobanking.
3. A statement that addresses the use of the subject’s associated personal health information and/or the subject’s identity with any future genomic testing or biobanking.
4. A plan for managing incidental findings, even if that plan is not to disclose any secondary or incidental findings. This plan should also be explained in the consent form. The templates have example language.
5. Research Conducted in a Foreign Country

Any project that will be conducted in whole, or in part, at a location outside the United States must include answers to the following questions:

* List the study location and the primary language/dialect spoken by the proposed subject population.
* If this project has been, or will be, reviewed by a local IRB or Ethics Committee, provide the name, address, and contact information for the local IRB or ethics review committee at the foreign research site.
* If applicable, provide the name and contact information for any foreign investigator, collaborator, or institution assisting the PI in the conduct of the project.
* Briefly describe your knowledge of the intended population including knowledge of local customs, practices, and religions as they relate to this project.
* Describe your proficiency with the local language, or how information and communication will be translated throughout the project.
* Describe how the community will be notified, and information disseminated, regarding the results of the research project.
* Address any cultural, regional, or unique risks the IRB should be aware of when evaluating this research project.
* State how will you communicate with the IRB if you need to report an unanticipated problem (associated with risk to subjects or others associated with the study) or an amendment to the study.
* For student investigators, explain how the faculty sponsor will provide oversight for the study while you (or representatives) are conducting the research in the foreign country.

1. Community-Based Participatory Research

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.