**INSTRUCTIONS:**

* Complete this Protocol Template only when there is **no** existing authored protocol provided for this study.
* If you are doing a data-only study with no prospective or interventional components, use the Data Only Protocol Template instead.
* This Protocol Template is to be used in conjunction with the SMART KP IRB Core Data Form.
* Enter your responses to each question directly below the BLUE text in the fillable field.
* When completing this Protocol Template, if a section does not apply to your study then enter “N/A.”

1. **Protocol**

Protocol Title

Click or tap here to enter text.

Principal Investigator

Click or tap here to enter text.

Version Date

Click or tap here to enter text.

Form Author

Click or tap here to enter text.

1. **Objectives**

Describe in plain language the purpose, specific aims, or objectives and indicate the primary goal(s) of the study (e.g. safety, tolerability, effectiveness, feasibility, pilot study, etc.). State the hypotheses to be tested. State primary and any secondary study endpoints.

Click or tap here to enter text.

1. **Background**
2. Scientific Background

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. A list of references or bibliography must be included as part of this document or uploaded separately.

Click or tap here to enter text.

1. Preliminary Data

Describe any relevant preliminary data.

Click or tap here to enter text.

1. **Study Design**

Describe the overall approach of the study (e.g. prospective, interventional, observational, retrospective, etc.). If your study includes more than one group, arm, or subject population, describe that here (for example, a study of both subjects and their caregivers, or a study with both a prospective interventional arm and a retrospective chart review arm).

Click or tap here to enter text.

1. **Study Population**
2. Number of Subjects

State the number (or approximate number, if appropriate) of subjects you plan to include at the KP region to which this study is being submitted. If applicable, distinguish between the number of subjects who are expected to be enrolled/screened and the number of subjects needed to complete the research procedures (e.g. numbers of subjects excluding screen failures).

As appropriate, consider different populations of subjects within the same study (e.g. subject/caregiver, parent/child, patient/physician). If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

Click or tap here to enter text.

1. Inclusion and Exclusion Criteria

* Describe the criteria that define who will be included or excluded in your final study sample.
* Describe how individuals will be screened for eligibility.
* Describe the plan for disposition of data collected during recruitment/screening in the event of a screen failure or when a potential subject is contacted but declines participation (e.g. destroyed immediately, destroyed at end of study, retained for separate analysis or so that subjects are not contacted repeatedly about participation after they have declined, etc.).

Click or tap here to enter text.

1. Vulnerable Populations

Indicate whether you will include or exclude each of the following special populations. This refers to subjects who are known members of these populations upon enrollment or at any time during the study. Justify the inclusion of any of these populations. Describe additional safeguards to protect the rights and welfare of these subjects.

* Children
* Pregnant Women
* Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)
* Prisoners (NOTE: The KP IRB does not have the appropriate membership to review research involving prisoners. Consultation with KFRI will be required.)

Click or tap here to enter text.

IMPORTANT NOTE: Consider whether subjects will be in a vulnerable category at the time of data collection or during analysis. For instance, if you collect data about children who were ages 12 – 15 from years 2000 – 2002, you know that now those individuals are no longer children.

Decisionally Impaired Adults

State whether decisionally impaired adults will be included and explain the extent of cognitive impairment (complete, fluctuating, progressive, or temporary). Justify their inclusion, and explain any protections to mitigate risk (such as the involvement of a caregiver or authorized representative). Describe consent/assent procedures.

Click or tap here to enter text.

Other Populations Targeted for Recruitment

If you are targeting a population that may be vulnerable to coercion or undue influence based on the specific circumstances of the study, describe how you will ensure that participation is voluntary and minimize any added risk. (Common examples include employees, students, people of low socioeconomic status, etc.)

Click or tap here to enter text.

1. Setting

Describe the sites or locations where your research team will conduct the research.

If this is a multi-site study:

* Specify what procedures are being performed at this site or by this site’s personnel (consider recruitment, consent process, study procedures, data analysis, etc.).
* State how each site will satisfy its IRB review requirements. Indicate if you are asking this site’s IRB to rely on another IRB or if another institution would like to rely on this site’s IRB and include this information in the eIRB Initial Project submission

For research conducted outside this site describe: (Community, Reservations etc.)

* Site-specific regulations or customs affecting the research at that location.
* Local scientific and ethical review structure outside this site.

Click or tap here to enter text.

1. Recruitment Methods

Describe how study participants will be recruited and enrolled. Indicate whether you will openly recruit using advertisements, websites, or brochures. Indicate if you plan to do targeted recruitment using existing records or referral. (Upload all recruitment materials to your submission to the IRB.)

Describe, by position/title, who will be recruiting and enrolling participants (providing the specific names of research team members is not necessary).

Describe any plans for the participants in the currently proposed study to be re-contacted or recruited for future follow-up studies. (Note that participants should be informed of this potential for re-recruitment during the current study’s consent process.)

Click or tap here to enter text.

1. Informed Consent Process

Describe how you will obtain and document consent, including:

* Where, when and how the consent process will take place.
* A process to ensure ongoing consent.
* Steps that will be taken to minimize the possibility of coercion or undue influence.
* Any steps that will be taken to ensure the subjects’ understanding.
* If you will conduct screening or any other research procedures before obtaining full informed consent, describe this.

Click or tap here to enter text.

Waiver of Informed Consent

Provide rationale and justification for the Waiver of Informed Consent for this study, including:

* Does the proposed research present no more than minimal risk to the study participants?
* How the waiver of informed consent will not adversely affect the rights and welfare of the participants.
* Why this research cannot practically be carried out without a waiver of informed consent.
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Click or tap here to enter text.

Waiver of Signed Informed Consent

Provide rationale and justification for the Waiver of Signed Informed Consent by identifying which of these two conditions applies and how.

1. The research involves no more than minimal risk to participants AND involves no procedures for which written consent is normally required outside of the research context.
2. The signed consent document would be the only record linking the participants to the research, and the principal risk to participants would be potential harm resulting from a breach of confidentiality.

Click or tap here to enter text.

Alteration of Informed Consent

Identify the required elements of informed consent that you wish to remove or alter. Provide justification for their removal or alteration.

Click or tap here to enter text.

Non-English-Speaking Subjects

If subjects who do not speak English will be enrolled, describe how the consent discussion will take place and indicate if translated consent forms or short forms will be used. Confirm that an interpreter will assist with the initial consent process and subsequent study visits.

Click or tap here to enter text.

Assent of Children and Parent Permission

IMPORTANT NOTE: Consent may be obtained in certain situations. For example, conducting family planning or sexually transmitted disease (STD) research. In addition, for older children ages 16 and up who participate in an adult study, the consent document can be used in place of the assent document.

Describe how you will obtain and document assent/parental permission, including:

* Describe your plan for obtaining parent permission. The permission of one parent is generally sufficient for minimal risk research, or for greater than minimal risk research if there is the potential for direct benefit to the child.
* Note that for studies involving greater than minimal risk with no prospect of direct benefit to the child, permission of both parents is required 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.
* Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission.
* Indicate whether assent will be obtained and documented from all, some, or none of the children. If assent will only be obtained from some children (because of very young age, severe cognitive impairment, etc.), indicate which children will be required to assent and which will not.
* When assent of children is obtained, describe whether and how it will be documented.
* When subjects might reach the age of majority during the study, describe the plan to obtain consent from these subjects at that time using an adult consent form.

Click or tap here to enter text.

Adults Unable to Consent/Decisionally Impaired

Describe the consent/assent process for Adults Unable to Consent/Decisionally Impaired, including:

* Describe the process to determine whether an individual is capable of 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.
* Describe the process for assent of the subjects. Address the following:
  + Whether assent will be required of all, some, or none of the subjects. If assent will be obtained from some subjects, indicate 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.
  + When assent is obtained, describe how it will be documented.
* Describe the plan to obtain consent if subjects might regain capacity to consent during the study.

Click or tap here to enter text.

1. HIPAA Privacy Rule Authorization – if study will use or disclose Protected Health Information (PHI)

Describe the plan to obtain a signed Privacy Rule Authorization from each subject.

Click or tap here to enter text.

Partial Waiver or Alteration of HIPAA Privacy Rule Authorization

If applicable to this study, explain your request for a Partial Waiver or Alteration of HIPAA Privacy Rule Authorization or if you want to eliminate any required language from the authorization, and provide the following rationale and justification.

* Why the research could not practicably be conducted without the waiver.
* Why access to and use of the PHI is necessary for the research.
* Why the use or disclosure of PHI for the research poses no more than minimal risk to the subjects' privacy (must have an adequate plan to protect the PHI from improper use or disclosure, a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research, and when applicable, written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity).

Click or tap here to enter text.

Full Waiver of HIPAA Privacy Rule Authorization

If you will not obtain a signed HIPAA Privacy Rule Authorization, provide the following rationale and justification.

* Why the research could not practicably be conducted without the waiver.
* Why access to and use of the PHI is necessary for the research.
* Why the use or disclosure of PHI for the research poses no more than minimal risk to the subjects' privacy (must have an adequate plan to protect the PHI from improper use or disclosure, a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research, and when applicable, written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity).

Click or tap here to enter text.

1. **Study Procedures**

Describe and explain the study design, including:

* Procedures to monitor subjects for safety, including who will review the data and at what frequency for safety issues.
* Procedures performed to lessen the probability or magnitude of risks.
* All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.
* The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
* What data will be collected including long-term follow-up.
* 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)

NOTE: It should be clear exactly which procedures will be conducted for the research as opposed to procedures the subjects would undergo (in the exact manner described in the protocol) even if they were not participating in the study.

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

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

Describe any procedures for orderly termination.

If the study involves genetic testing or collection of genetic information, describe this.

Click or tap here to enter text.

1. Data Analysis

Describe the data analysis plan, including:

* Statistical procedures.
* When applicable, the power analysis.
* Any procedures that will be used for quality control of collected data.

Click or tap here to enter text.

1. Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of standard or research lab tests and genetic tests) will be shared with subjects or their providers.

If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

If laboratory results will be shared with subjects or their healthcare providers, verify that the laboratory conducting the test is Clinical Laboratory Improvement Amendments (CLIA) certified.

Click or tap here to enter text.

1. Data and/or Specimen Banking

Indicate if specimens may be used for future research and whether that may include genetic research.

State if data or specimens will be sent to a separate repository. If data or specimens will be banked in a repository for future use as part of this protocol submission address the following questions:

* What will be banked and what identifiers will be associated with the data or specimens?
* Where and how will the data or specimens be stored?
* For what purpose will the data or specimens be used?
* How will the data or specimens be accessed, and who will have access?
* 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.

Click or tap here to enter text.

1. **Privacy, Confidentiality and Data Security**

Describe the steps that will be taken to protect subjects’ privacy during recruitment, consent and study procedures.

Click or tap here to enter text.

Describe the plan for storage of data and/or specimens.

* Who will have access and how.
* Where the data/materials will be stored and for how long.
* What identifiers will be included.
* Any other steps that will be taken to ensure security (e.g., training of staff, authorization of access, password protection, encryption, physical security, and separation of identifiers from data and specimens, certificates of confidentiality).
* Describe the plan to destroy/archive or retain data at the end of the study.

Click or tap here to enter text.

Collection of data from subjects electronically

If you will collect any data from participants electronically (including email, website, etc.), explain:

* How the data will be collected.
* How the information will be secured (encryption, password protection, etc.; may require consultation with IT department).
* Any risks to the participants’ privacy posed by using these methods (describe in consent, as applicable).
* How you will verify the participant’s identity.

Click or tap here to enter text.

Does this study involve the disclosure of PHI to a collaborator?

If any data will be sent outside of this site, list each recipient (may list by role or category if the information is the same for several different entities). For each recipient, describe:

* What will be sent.
* Whether the information will be fully identifiable (PHI, if health information), a Limited Data Set, de-identified, or aggregate.
* How the data/materials will be transferred securely (for instance, Secure File Transfer).

Click or tap here to enter text.

1. **Provisions to Monitor Data to Ensure the Safety of Subjects**

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

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Describe:

* Who will monitor the study data for safety?
* The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
* 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.
* The frequency or periodicity of review of cumulative data.
* Criteria for taking action on monitoring findings (for instance, stopping rules, immediate suspension, reporting, protocol changes, changes to monitoring frequency or plan).
* For studies monitored by a DSMB/C, describe the committee membership and structure, meeting format, and quorum requirements. Upload the board/committee charter, if one exists.

Click or tap here to enter text.

1. **Risks and Benefits**
2. Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Describe 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 should the subject be or become pregnant.
* If applicable, describe risks to others who are not subjects and risks to Kaiser Permanente

Click or tap here to enter text.

1. Potential Benefits to Subjects

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

Click or tap here to enter text.

1. **Economic Burden to Subjects**

Describe any costs that subjects may be responsible for because of participation in the research study (for example, co-pays; paying for treatment, therapies, or other interventions, or the delivery of these) and how you will inform participants of these costs prior to their enrollment in this study.

Click or tap here to enter text.

1. **Compensation to Participants**

Describe any compensation provided to participants, for example, for time inconvenience, discomfort, travel, or in the event of research related injury. If applicable, describe how you will inform participants of this prior to their enrollment in the study, including if payment will be prorated if the subject withdraws early from the study.

NOTE: payment may not be withheld as an incentive for participants to complete the study.

Click or tap here to enter text.

1. **Resources Available**

Describe any special resources or expertise required to conduct the study.

Click or tap here to enter text.

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.)

Click or tap here to enter text.

1. **Drugs or Devices**

NOTE: see the ICH-GCP guidance for a summary of investigator and sponsor responsibilities in clinical trials.

1. Drug Studies

If the research involves drugs and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a new drug application [NDA]).

* + If the drug is investigational (has an IND), confirm that you will comply with all applicable FDA requirements for investigators.
  + Confirm that you will follow applicable KP pharmacy policies and procedures.
  + Describe your plan for drug storage, handling, and accountability, including distribution, return, and destruction of the drug(s).

Click or tap here to enter text.

1. Device Studies:

If this is a device study and you think the device is Non-Significant Risk, include justification here or upload it as a separate document along with any available device information (instructions for use, etc.).

If the research involves devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a premarket approval application [PMA]).

* If the device has an IDE or a claim of abbreviated IDE (Non-Significant Risk device), confirm that you will comply with all applicable FDA requirements for investigators.
* Describe the device, the manufacturing process, and the device labeling, including safety instructions or warnings. If available, this may be addressed in separately uploaded device information (such as instructions for use).
* Describe device storage, handling, and accountability, including how access to the device will be limited to appropriate personnel and how you will ensure the device will be used only for appropriate study subjects.

Click or tap here to enter text.

1. **Multi-Site Research** 
   1. If this is a multi-site study and you are the lead investigator or this site will be the coordinating center for any activity, 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 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.
  1. Describe the method for communicating to engaged participating sites the following:
* Problems.
* Interim results.
* The closure of a study.
  1. Describe any special resources or expertise required to conduct the study.

Click or tap here to enter text.

1. **Community-Based Participatory Research**

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

Describe your plan for ensuring that community research partners are appropriately trained in human subjects’ protection.

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.

Click or tap here to enter text.