**HRP-503-TEMPLATE PROTOCOL-Drugs Devices Clinical Interventions**

* *Use this template when no sponsor-authored protocol is available and the study directs the use of drugs, devices,* *or other clinical interventions (e.g., medical imaging) for research purposes.*
* *Please take time to read all italicized instructions prior to submission.*
* ***Delete the red italicized instructions before submitting to the IRB.***
* *Depending on the nature of the research, some sections may not be applicable to your research. If not applicable, reply with “N/A.”*
* *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
1. **Protocol Title**
2. Title:
3. Protocol Version Date:
4. **Objectives**
5. Describe the purpose, specific aims, or objectives:
6. State the hypotheses to be tested:
7. Describe how this research will add to existing knowledge or how the outcomes of this project will be used:
8. **Enrollment Numbers**
9. Total number of subjects to be enrolled in this study:
10. If this is reliance, list the number of subjects to be enrolled at each site (UC Davis: #, Relying Site 1: #, Relying site 2: #)
11. Provide a rationale (e.g., statistical justification, power analysis, etc. for the number of subjects to be enrolled:
12. **Inclusion and Exclusion Criteria**
13. Inclusion Criteria:
14. Exclusion Criteria:
15. Age Range:
16. If applicable, describe the screening procedures to determine eligibility:
17. Contraceptive Requirements

*When the study directed procedures include the use of an investigational drug or device known to harm an embryo or fetus or it is reasonable to believe such a risk exists, appropriate contraceptive methods are required.*

[ ]  N/A - This research does not require contraception. Skip to the next section.

a)      Who is Considered Unable to Become Pregnant?

For participants in this research, the following persons are considered *unable to become pregnant* from sex. People unable to become pregnant from sex will not be required to use contraception. These criteria apply to a participant or the sexual partner of a participant.

* Someone without a uterus or any ovaries.
* Someone who has had surgery to remove or block their fallopian tubes.
* Someone who no longer has their period because of menopause.
* Someone who only has sex with partners who do not produce sperm.

1. Contraceptive Methods Acceptable for This Study:

The following contraceptive methods are categorized by their effectiveness with typical use. Select the appropriate contraceptive requirement for this research. For studies involving investigational new drugs, information about contraception requirements may be found in the Investigator’s Brochure.

During the screening process the study team will inform participants of the acceptable contraceptive options for this study and confirm that the participant’s selected contraceptive method is appropriate and safe, especially for estrogen-containing contraceptives. Investigators are encouraged to use the U.S. [CDC Medical Eligibility Criteria](https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm) or consult with a Complex Family Planning Specialist in the Department of Obstetrics and Gynecology if more information is needed.

*Mark all boxes appropriate for this study.*

☐ HIGHLY effective contraception

* Contraceptive implant
* Intrauterine device
* Vasectomy
* Surgery to remove or block the fallopian tubes (tubes “tied”)

☐ MODERATELY effective contraception

·         Oral contraceptives with estrogen

·         Oral contraceptives without estrogen

·         Vaginal ring

·         Transdermal patch

·         Injectables

☐ Check this box if a condom will be required to be used with a moderately effective method.

**NOTES ABOUT CONDOMS**

* Requiring condom use with a highly effective method to “increase” contraceptive efficacy does not work and cannot be required.
* Using a barrier method in addition to a moderately effective method will slightly increase overall effectiveness but will not create a highly effective method.
* Using “double-barrier” methods do not create a moderately effective method.
* In some cases, condom use may be required to protect the partner of a research participant from possible exposure to harmful substances. This is addressed in the “Risk to Subjects” section.
1. **Procedures Involved**

*Describe and explain the study design:*

* *All research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.*
* *The procedures being performed already for diagnostic or treatment purposes.*
* *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. (Upload all surveys, scripts, and data collection forms to IRBNet.)*
* *What data will be collected including long-term follow-up.*
* *How much blood is being drawn and how often.*
* *The data analysis plan, including any statistical procedures.*
* *Any procedures that will be used for quality control of collected data and/or specimens.*
1. **Study Timelines**
2. Duration of an individual subject’s participation in the study:
3. Estimated timeline to enroll all study subjects:
4. Estimated timeline for the investigators to complete this study (complete primary analyses):
5. **Study Endpoints**
6. Describe the primary and secondary study endpoints:
7. Describe any primary or secondary safety endpoints:
8. **Recordings**

This research involves:

[ ]  Audio recordings

[ ]  Photographs

[ ]  Video recordings with audio

[ ]  Video recordings without audio

[ ]  None of the above

1. **Data and/or Specimen Management and Confidentiality**

Before completing this section, see [Privacy and Confidentiality](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/privacy-and-confidentiality/) and [HIPAA Guidance](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/medical-records/#What%20types%20of%20information%20are%20regulated%20by%20the%20Privacy%20and%20Security%20Rules).

1. List any identifiers that will be collected during the course of this study (e.g., name, medical record number, date of birth, video recordings, etc.):
2. If any identifiers will be stored, how long will they be kept?
3. For data that is coded with a linking key, at what point will the linking key be destroyed?
4. For any recordings, at what point will the recordings be destroyed?
5. If this research is both federally funded *and* you are using identifiable data/specimens, please explain why this research cannot be completed using de-identified data/specimens:

**NOTES ABOUT USE OF RECORDS**

UC Davis Medical Records: UC Davis Health Electronic Health Record (EMR/EPIC) also contains the clinical data for Marshall Medical Center (MMC). MMC patient data cannot be accessed for research purposes. Researchers must take the necessary steps to ensure that MMC data is not accessed, used, or disclosed for UC Davis Health research purposes.

If protected health information or personal information from the medical records will be stored on an encrypted device, investigators must follow applicable university policies (UC Davis Hospital Policy 1313, UCDHS P&P 2300-2499, and UC Business and Finance Bulletin on Information Security (IS-3)). Please contact the [Biomedical Informatics Department](https://health.ucdavis.edu/ctsc/area/informatics/index.html) for assistance with data security.

If identifiable protected health information is extracted from the UCDH EMR, it may not be re-disclosed/released outside the study team.

UC Davis Student Education Records: If this study involves use of UC Davis students’ educational records (including records in the PI’s own possession such as course exams/assignments), you must consult with the Registrar’s office to see if all requirements of the Family Educational Rights and Privacy Act (FERPA) are satisfied.

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

*A monitoring plan 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. See* [*Monitoring for Safety and Compliance*](https://irb.ucdavis.edu/project-guidance/monitoring/) *for more information.*

*Describe:*

* *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.*
* *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.*
1. **Withdrawal of Subjects**

*Describe:*

* *Anticipated circumstances under which subjects will be withdrawn from the research without their consent.*
* *Procedures for orderly termination.*
* *Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*
1. **Risks to Subjects**

[ ]  This research may pose the risk of loss of confidentiality. The risk will be minimized through the data protection plan.

*List any other reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, 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.*

Semen Protection Unrelated to Contraception

*In some cases, transmission of protocol required drugs through semen may be harmful to sexual partners of study participants. In these cases, requiring use of a condom for all sexual acts reduces the risk of exposure to a potentially harmful substance.*

*Mark one of the following boxes as appropriate for this study.*

☐ Condom use will be required for any sexual acts to minimize semen exposure.

A risk exists that could be harmful to a sexual partner exposed to semen. Study subjects with a penis will be instructed to remain abstinent or use a condom, even if they have undergone a vasectomy. Study participants will be instructed to refrain from donating sperm during study treatment and for a specified period after stopping the study treatment.

☐    Condom use will not be required for any sexual acts to minimize semen exposure (unrelated to contraception).

1. **Potential Benefits to Subjects**

[ ]  Research subjects are not likely to receive any benefit from the proposed research, but others may benefit from the knowledge obtained.

*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.* *Do not include monetary reimbursement, free clinic visits, or other incentives in this section.*

1. **Provisions to Protect the Privacy Interests of Subjects**

*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 to whom they provide personal information.*

*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.*

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

1. **Sharing of Results with Subjects**

[ ]  Results will not be shared with subjects

[ ]  Results will be shared with subjects - Describe:

1. If results will be shared, describe the results (study results or individual subject results such as results of investigational diagnostic tests, genetic tests, or incidental findings) to be shared with subjects or others (e.g., the subject’s primary care physicians).

Note: There are restrictions on the information that can be provided to individuals when the tests performed on their specimens are considered investigational or the tests are not being performed at a CLIA-certified laboratory.

1. **Data/Specimen Banking**
2. Will the data or specimens ever be used by you or other researchers to answer a different research aim that is not included in this study?

[ ]  Yes - Complete the remainder of Section 16.

[ ]  No - Do not complete Section 16. Go to next section.

1. What will be banked for future use?

[ ]  De-identified data/specimens. Banked data/specimens cannot be linked to an individual.

[ ]  Identifiable data/specimens – Banked data/specimens will include identifying information.

[ ]  Coded data/specimens – Banked data/specimens will be stripped of identifiers and assigned a code. A key will be maintained that links the identifiers to the data/specimens.

[ ]  Contact information will be banked for future research opportunities.

1. Where will the data/specimens be banked?
2. How long will the data/specimens be banked?
3. Who will have access to the banked data/specimens?
4. Describe the procedures to release data/specimens. Include the process to request a release, approvals required for release, who can obtain data/specimens, and the data/specimens to be provided.

Note: Identifiable protected health information extracted from the UCDH EMR under an IRB-issued waiver of HIPAA Authorization may not be re-disclosed/released outside the study team.

1. **Multi-Site 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 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. **Community-Based Participatory 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.*

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

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, 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. **Review Requirements**

Some research projects require specific IRB determinations.

1. Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA?

[ ]  Yes

[ ]  No

1. If yes, please describe: