**HRP-503-TEMPLATE PROTOCOL-Surveys Interviews Questionnaires Focus Groups**

* *This template is for research that involves surveys, interviews, focus groups, and observational research.* ***If your proposed project involves any activities other than surveys, interviews, focus groups, or observations, do not use this form.***
* *Please take the time to read all italicized instructions and questions.*
* ***Delete the 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.”*
* *Studies involving only interviews, surveys, focus groups, or observation are often exempt. Please use HRP-502 Consent Templates for Exempt Research or an oral consent process that includes the following information:*
	+ *The subject is being asked to participate in a research study;*
	+ *A description of the procedure(s) the participant will be asked to complete;*
	+ *Participation is voluntary; and*
	+ *The investigator’s name and contact information.*
* *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. **Background**
8. Describe the relevant prior experience and gaps in current knowledge:
9. Describe any relevant preliminary data:
10. Describe how this research will add to existing knowledge or how the outcomes of this project will be used:
11. **Enrollment Numbers**
12. Total number of subjects to be enrolled in this study:
13. If this is a reliance, list the number of subjects to be enrolled at each site, by site. (UC Davis: #, Relying Site 1: #, Relying Site 2: #)
14. Provide a rationale (e.g. statistical justification, power analysis) for the number of subjects to be enrolled.
15. **Inclusion and Exclusion Criteria**
16. Inclusion Criteria:
17. Exclusion Criteria:
18. Age Range:
19. If applicable, describe the screening procedures that you will use to collect data:
20. **Procedures Involved**

[ ]  Surveys – Upload all surveys you will use in this study to IRBNet.

[ ]  Interviews – Upload an interview script with the questions that will be asked during the interview to IRBNet.

[ ]  Focus groups – Upload a summary of the questions and issues that will be discussed during the focus sessions to IRBNet.

[ ]  Observation

1. Describe the behavior you will be observing and the setting of the observation:
2. Describe what you will be collecting or documenting for the research:

[ ]  Other

1. Describe any other data collection or research procedures you will be conducting:
2. **Study Timelines**
3. Duration of an individual subject’s participation in the study:
4. Estimated timeline to enroll all study subjects:
5. **Recordings**

This research involves:

[ ]  Audio recordings

[ ]  Photographs

[ ]  Video recordings with audio

[ ]  Video recordings without audio

[ ]  None of the above

1. **Data Management and Confidentiality**

Before completing this section, see [Privacy and Confidentiality](https://irb.ucdavis.edu/project-guidance/privacy-and-confidentiality/) and [HIPAA Guidance](https://irb.ucdavis.edu/project-guidance/medical-records/#what_types_of_info_reg_by_HIPAA).

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?

**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/) 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. **Risks to Subjects**

[ ]  This research may pose the risk of loss of confidentiality. The risk will be minimized through the processes described above. This study will abide by all applicable law, regulations, and standard operating governing the protection of human subjects, student information and protected health information.

[ ]  Other – Describe:

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.

[ ]  Other – Describe:

1. **Sharing Results with Subjects**

[ ]  Results will not be shared with subjects.

[ ]  Results will be shared with subjects.

1. If results will be shared, describe the results (study results or individual subject results) to be shared with subjects or others (e.g., the subject’s primary care physicians):
2. **Data Banking**
3. Will the data 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 13.

[ ]  No – Do not complete Section 13. Go to Section 14.

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 be banked?
2. How long will the data be banked?
3. Who will have access to the banked data?
4. Describe the procedures to release data. Include the process to request a release, approvals required for release, who can obtain data, and the data 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. **Review Requirement**

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: