**HRP-503-TEMPLATE PROTOCOL-Secondary Data Analysis**

* *This template is for secondary analysis research that involves the use of records, data, or specimens that were collected for other purposes.*
* *Please take the time to read all italicized instructions and questions.*
* ***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. **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. **Number of Individual Records/Specimens**
12. Total number of records/specimens to be used:
13. If this is a reliance, list the number of records/specimens to be reviewed for each site, by site. (UC Davis: #, Relying Site 1: #, Relying Site 2: #)
14. Provide a rationale (e.g. statistical justification) for the number of records/specimens to be used:
15. **Inclusion and Exclusion Criteria**
16. Inclusion Criteria:
17. Exclusion Criteria:
18. Age Range:
19. **Procedures Involved**
20. Describe and explain the study design, statistical analysis and study endpoints:
21. **Recordings**

This research involves:

[ ]  Audio recordings

[ ]  Photographs

[ ]  Video recordings with audio

[ ]  Video recordings without audio

[ ]  None of the above

1. **Source of Data/Specimens**
2. What is the source of the data/specimens?

[ ]  UC Davis/UCDMC

[ ]  Outside of UC Davis

1. Type of data/specimens:

[ ]  Publicly available records

[ ]  Educational Records

[ ]  Medical Records

[ ]  Leftover specimen from clinical care

[ ]  Research records/specimens collected during a different research project.

[ ]  Other - Describe:

**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. **Secondary Analysis of Existing Research Records/Specimens**

If you selected “Research records/specimens collected during a different research project” above, review the original research protocol and consent document to answer the questions below.

|  |  |  |
| --- | --- | --- |
| Yes | No | Origin of Research Data/Specimens |
| [ ]  | [ ]  | Does the original protocol and/or consent document prohibit the release of these data/specimens in the format (identifiable, coded, or anonymous) you plan to obtain them? |
| [ ]  | [ ]  | Does the original protocol and/or consent document specifically allow the use of the data/specimens for this newly proposed research? |
| [ ]  | [ ]  | Does the original study have a Certificate of Confidentiality?Note: If the original study has a Certificate of Confidentiality, subject identifiers cannot be shared outside of the study. |
| [ ]  | [ ]  | Is any member of this research team also part of the original research? |

1. **Date of Creation of Data/Specimens**

The data/specimens to be analyzed were/will be originally created from *Month/Year* to *Month/Year*.

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?
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:
6. **Data Collection Form**

Provide your data collection form or a list of the data elements you will be recording.

The data collection form will be uploaded to IRBNet.

[ ]  Yes

[ ]  No or N/A

1. **Machine Learning**

Does this project involve a machine learning algorithm that will be used to guide clinical care?

[ ]  Yes

[ ]  No

1. **Risks to Subjects**

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

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. **Privacy Interests of the Subjects**
2. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.
3. Research subjects will be contacted regarding this research:

[ ]  Yes

[ ]  No

1. If yes, describe the steps that you will take to protect subjects’ privacy interests:
2. **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 18.

[ ]  No - Do not complete Section 18. Go to section 19.

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. **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: