**HRP-503-TEMPLATE PROTOCOL-UCDH Chart Review**

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| **Yes** | **No** | **Use of this Template** |
| [ ]  | [ ]  | 1. Is this research federally funded?

If yes, stop. Federally funded research requires additional IRB determinations. If this research is limited to secondary analysis, please complete the [HRP-503 Record/Data/Specimen Secondary Analysis Review Template](https://irb.ucdavis.edu/wp-content/uploads/HRP-503-TEMPLATE-PROTOCOL-Record-Data-Specimen-Review.docx). |
| [ ]  | [ ]  | 1. This research will use only data collected from the UCD Health EMR. No other data will be collected and there are no other study procedures for this research.

If no, stop. This template is for medical record review of UCDH EMR data only. The research may not include data collected through any other procedure. The research cannot involve data collected for non-clinical purposes (research interviews or surveys), data for another research study, or data released from another institution (e.g., via Data Use Agreement). If this research involves a data source other than the UCDH EMR, please complete the [HRP-503 Record/Data/Specimen Secondary Analysis Review Template](https://irb.ucdavis.edu/wp-content/uploads/HRP-503-TEMPLATE-PROTOCOL-Record-Data-Specimen-Review.docx). |

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. **HIPAA Protected Health Information (PHI) obtained from UC Davis Health**

Protected health information (PHI) is defined by HIPAA as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates. As a healthcare provider, UC Davis Health is a covered entity obligated to protect PHI. Access, disclosure, or use of PHI for research purposes requires a signed HIPAA Authorization or IRB-issued waiver of HIPAA Authorization. When PHI is extracted from the UCDH Epic EMR, it may not be re-disclosed/released outside the study team.

Under HIPAA, any data set which contains any one of the 18 HIPAA identifiers listed below is considered an identifiable data set. If a data set extracted from UCDH Epic EMR includes any of the 18 HIPAA identifiers, this means that it is PHI. To be considered a de-identified data set, at a minimum, all of the listed 18 HIPAA identifiers must be omitted from the dataset.

Data that is derivative of any of the 18 HIPAA identifiers (e.g., initials instead of name or partial phone number) is still considered identifiable. Check the box next to any identifier that will be documented in research records. If a derivative of an identifier will be documented, check the box next to the associated identifier. For example, if you are documenting the last four digits of subjects’ social security numbers, please check social security numbers. If none of these will be documented in research records, select “None of the above.”

[ ]  Names

[ ]  Telephone numbers

[ ]  Fax numbers

[ ]  Email addresses

[ ]  Social Security numbers

[ ]  Medical record numbers

[ ]  Health plan beneficiary

[ ]  Vehicle identifiers and serial numbers, including license plate numbers

[ ]  Account numbers

[ ]  Certificate/license numbers

[ ]  Device identifiers and serial numbers

[ ]  Web Universal Resource Locators (URLs)

[ ]  Internet Protocol (IP) addresses

[ ]  Biometric identifiers, including finger and voice prints

[ ]  Full-face photographs and any comparable images

[ ]  Geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:

* The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
* The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.

[ ]  Elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

[ ]  Any other unique identifying number, characteristic, or code, unless otherwise permitted by the [Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html) for re-identification.

[ ]  None of the above

1. **Description of Data Elements**

In the space below, describe any additional data elements that will be accessed and used for this research or upload your data collection form as a separate document to IRBNet.

**NOTES ABOUT USE OF RECORDS AND DATA CONFIDENTIALITY**

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 PHI will be documented in research records, researchers should remove and destroy identifiers at the earliest possible opportunity consistent with the conduct of the research. In the Data Confidentiality section of the Initial Review Application, you will indicate how data is to be maintained for this research. The Initial Review Application’s options for data maintenance are listed below. Unless there is a justifiable reason why data for this research must be maintained in an identifiable format, the expectation is that data will be maintained in one of the three other formats listed (i.e., coded with a linking key, coded without a linking key, or with all identifiers destroyed).

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| **Definitions** |
| * **Identifiable**

Data or specimens will be labeled with identifying information.* **Coded with linking key**
* Data will be stripped of identifiers and assigned a code. The research team will maintain a key that links the identifiers to the data set.
* **Coded without linking key**

Data will be stripped of identifiers and assigned a code. The research team will not have access to a key that links the identifiers to the data set and will not attempt to re-identify the data.* **All identifiers will be destroyed**

There will be no way to link the data to an individual. |

If the data will be coded, the codes cannot be derived from any identifiers related to the individual nor to the linking list. For example, a subject's initials cannot be used as part of the code, because the initials are derived from the subjects’ name, and therefore still considered identifiable under the HIPAA PHI definition. In addition, the method to derive the unique codes cannot be disclosed.

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.