

## Data Management Plan – Chart Review Study

**\*\* Specifics may vary by institution \*\***

Title of Project:

Principal Investigator:

Person completing this form (Name and email):

Hospital (entity that maintains/owns the data):

Duration of study (Anticipated start/end date):

This chart review study will include the collection and exporting of patient records into a REDCap database. The hospital research approval entity (e.g., research committee) will approve the study prior to any data exporting. All investigators will be either hospital faculty, staff, or university faculty. The following provides an overview of the data management process.

### Data Description:

The data to be gathered will be patient data residing in the hospital electronic medical record (EMR) system. The specific variables to be obtained are listed in the study protocol document. The patient medical record number will be collected along with the study variables. The patient medical record number along with all other personal health identifying (PHIs) variables will be tagged in the database as PHIs. Only study investigators who have been credentialed by the hospital to access patient information, will have access to all variables including PHIs. Study investigators who are not credentialed by the hospital to access data will have access to all variables, EXCEPT PHIs.

### Data Collection Process:

The data will be captured in a REDCap database. The data will be entered into the REDCap database using two methods. First, from a hospital computer, data will 1) be exported to an Excel file, and 2) imported into the REDCap database. Once imported into REDCap, the Excel file will be deleted. The second method includes manual entry from the EMR to the REDCap database. In this instance, a hospital credentialed investigator will review the EMR data, and manually enter information into the REDCap database. This will be performed on a hospital, or university computer. Note that hospital and university computers should be encrypted. Once data has been imported into REDCap the records status will be changed from *incomplete* to *unverified*. See Quality Assurance section for process of changing record status to *complete*.

**Existing Data:**

Data to be collected is existing data contained in the hospital EMR system. The hospital generally owns the data. On an annual basis, the hospital conducts credentialing of medical students and residents. This credentialing process includes the ability to access patient records maintained in the hospital EMR. With this credentialing, the residents are approved to access the data.

**Data Format:**

Data will be temporarily formatted into an Excel file. It will be then imported and maintained in a REDCap database. Upon being imported into the REDCap database, the Excel file will be deleted.

**Data Sharing:**

It is expected that the data from the REDCap database will be exported to SPSS for data analysis. Any data exported to SPSS will NOT contain any PHIs. This data file may be transmitted by email within the investigator team. If shared by email, the instigator sending the message will include the word **[safe]** (including the brackets) in the subject line to ensure the message is encrypted. In addition, if required by the conference or journal (all dissemination mechanisms), a pdf file would be created non-PHI data file. Hospital research approval group will approve any sharing process prior to actual dissemination.

**Data Access:**

Only study investigators will have access to the REDCap database. Investigators who have been credentialed by the hospital, will have access to the entire database. Investigators not credentialed, will have access only to study variables but not PHIs. Management of access will be performed at the user level in REDCap. Access to the data will be limited to the duration of the study, and subsequent completion of dissemination via conference or journal publication. Upon dissemination of any report, investigator rights will be removed from the REDCap database. Only the PI will have access to the database, post study. Data will not be available to individuals outside the study team.

**Data Storage:**

Data will be stored in a REDCap database. Any data file exported for data analysis purposes, may reside on any of the investigators work computers. Note that this data file will not contain any PHIs.

**Data Organization:**

All study data will be maintained in a REDCap database. The naming of the database will be aligned with the project title.

**Data Archive and Preservation:**

Upon the completion of the study, the REDCap database will be maintained for the time period required by research integrity (typically three years).

**Data Backup:**

The REDCap database will not be backed up by any study investigator.

**Quality Assurance:**

To ensure data is accurately transferred and/or entered into the REDCap database, source data verification (SDV) will be performed. Specifically, on a recurring basis, an investigator will review contents of the EMR and the REDCap database to ensure accuracy. The investigator performing the SDV, will not be the same investigator who entered the original information. Upon completion of the SDV process, the record status will be changed to *complete*. It is planned that at least 20% of the records will be SDVd. If an error rate exceeds 10%, SDV will be conducted on 100% of the data.

**Security and Compliance:**

Security compliance will be performed by the PI, or research methodologist. This investigator will identify roles, provide appropriate level access to the data, and update access on a monthly basis. Individuals who leave the study team, will be removed from data access. In the event the PI and research methodologist leave the team, security compliance will become the responsibility of the resident Program Director.