

StDavid's HEALTHCARE

Institutional Review Board

Medical Record Review Study Protocol

Principal Investigator:

Sub Investigators:

Address:

Study Title:

Site(s) where study will be performed:

Protocol Version-Date: V0.1 – December 15, 2016

1.0 Introduction - Background and Rationale *(include references)*

2.0 Hypothesis/Key Questions *(the hypothesis being evaluated; the key questions being asked in the research)*

3.0 Objectives *(Primary endpoints of study, listed and numbered individually)*

4.0 Selection of Patients

4.1 Inclusion Criteria:

4.2 Exclusion Criteria:

4.3 Age Range:

5.0 Indicate if this is a retrospective and/or prospective chart review

5.1 _____ **Retrospective Chart Review** (Retrospective means the data is already in existence when the project is submitted to the IRB for initial review.)

6.2 _____ **Prospective Chart Review** (Prospective means the data is not in existence when the project is submitted to the IRB for initial review)

5.3 Provide the date range of the chart review (if this is a retrospective chart review, the end date must come before the IRB submission date): *mm/dd/yyyy to mm/dd/yyyy*

6.0 Study Methods

6.1 Source (location) of records to be reviewed:

6.2 Describe how the charts to be reviewed will be identified:

6.3 Describe who will identify charts to be reviewed:

7.0 Confidentiality of data

7.1 Describe how data (both paper and electronic) will be stored to safe-guard confidentiality (e.g. in a locked cabinet, password protected computer):

7.2 Specify who will have access to harvested patient data:

7.3 Clarify how long collected patient data will be stored and how it will be destroyed when no longer needed:

8.0 Consent: *(Describe the type of consent to be obtained and justification for the choice [written, waiver, or verbal]. For additional information, please see the IRB Guidance on Medical Records Reviews. If requesting a Waiver of HIPAA*

Authorization, please complete the IRB Waiver of Authorization Template)

9.0 Risks and Benefits: *(modify as needed)*

9.1 Risks: e.g. A confidentiality breach is a risk associated with chart review research

9.2 Benefits: e.g. The subject's whose charts are reviewed are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

10.0 Statistical Considerations

10.1 Proposed sample size (number of records to be reviewed):

10.2 Proposed time period to be evaluated:

10.3 Specify how data will be analyzed and by whom:

11.0 Appendices: The following appendices must be attached to the protocol

11.1 Appendix A: Data Collection Form (This form should list the data elements that will be collected from the medical record. It should not contain any direct or indirect identifiers except for a unique subject code.)

11.2 Appendix B: Coded Identifier List (This form should serve as the link between the unique subject code and any identifiers you will need to conduct this chart review study [e.g., name, medical record number, date of birth, address, telephone number, social security number])

APPENDIX A: DATA COLLECTION FORM

- 1. Unique Subject Code**
- 2. List all elements to be collected during the chart review**

APPENDIX B: CODED IDENTIFIER LIST

1. **Unique Subject Code**
2. **Check all identifiers to be collected or used in this study** (e.g., name, medical record number, date of birth, address, telephone number, social security number)

Check all that will be used	Identifier
	Names
	All 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: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
	All 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
	Telephone numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Fax numbers
	Device identifiers and serial numbers
	Email addresses
	Web Universal Resource Locators (URLs)
	Social security numbers
	Internet Protocol (IP) addresses
	Medical record numbers
	Biometric identifiers, including finger and voice prints
	Health plan beneficiary numbers
	Full-face photographs and any comparable images
	Account numbers
	Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
	Certificate/license numbers