**CHART REVIEW PROTOCOL**
**Retrospective/Prospective**

**Principal Investigator:**
**Address:**
**IRB Project Title:**
**Site(s) where study will be performed:**
**Protocol Version Date:**

**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:**

*Note: With regard to research involving pregnant women, prisoners, or minors, the IRB must review the study in accordance with Subparts B, C or D of the federal regulations. If it can be presumed that the subjects are not pregnant, incarcerated, or under the age of 18 during the conduct of the chart review, the Subparts do not apply. If, however, during the course of the chart review, the investigator becomes aware that the subjects meet one or more of these conditions, the PI must either exclude such subjects from the dataset, or the IRB must promptly re-review the proposal in accordance with the requirements of Subparts B, C or D.*

**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 long harvested 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 Guidance and Instructions at the end of the protocol. Note: Illinois state law requires written consent for research which collects data related to HIV/AIDS, genetic information, mental health information and substance abuse information.)*

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

**9.1** Risks: A confidentiality breach is a risk associated with chart review research

**9.2** Benefits: 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])