Detailed Checklist for Chart Review Summary

(Do not submit this checklist as a part of your proposal.)

Title Page

Protocol title (must match title on consent form) and signature of Principal Investigator(s) and Principal Investigator’s SLEH Chief of Service

Research Protocol

1. Title: (must match title on consent form & on title page)

2 Principal Investigator: Principal investigator’s name, mailing address, phone number and e-mail address

3. Co-Investigator(s): List all co-investigators (their contact information is not necessary here)

4. Consultant(s): List all consultants (their contact information is not necessary)

5. Departments Involved: List all departments involved in research

6. Time Period: Records will be reviewed for patients admitted between Month/Year – Month/Year for this study.

7. Will any data be collected prospectively? (Not in medical record as date of proposal.)

8. Institution(s) where research is to be performed: List names of institutions covered by this protocol submission.

9. Outline of research proposal:

Background Information:

Purpose of Project:

Study Description: (Must include the following)

* Objectives & Endpoints
* Subjects (gender, age, ethnicity, primary language, groups that will be recruited & will vulnerable populations be recruited as subjects)
* Design (retrospective or prospective chart review)
* Inclusion/Exclusion Criteria
* Sources of data (ChartMaxx, THI Research Database, etc.)
* Sample size
* Data Analysis (Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?)

Subject Population:

Consent Procedures: (Is waiver of consent being requested? If so, complete the IRB Waiver of HIPAA Privacy Authorization and Informed Consent.)

Confidentiality: (How will patient’s confidentiality be protected?)

If a waiver is being requested, submit the IRB Waiver of HIPAA Privacy Authorization and Informed Consent. If a waiver is not being submitted, PHI must not be collected.)

**PROTOCOL TITLE**

(name)

Principal Investigator

Approved:

(name)

Chief, xxxxx Service

##### Research Protocol

1. **Title:**
2. **Principal Investigator:** *Name*

*Mailing Address*

*Phone / E-mail*

1. **Co-Investigators:**
2. **Consultants:**
3. **Departments involved:**
4. **Time period:** *Records will be reviewed for patients admitted between Month/Year – Month/Year for this study.*
5. **Will any data be collected prospectively?** *Yes / No*
6. **Institution(s) where research is to be performed:**

*St. Luke’s Episcopal Hospital*

*Texas Heart Institute*

1. **Outline of research proposal:**

Background information:

Purpose of project:

Study description:

Subject population:

Consent Procedures:

❑ Patients signed an informed consent to be included in the database at the time of evaluation for \_\_\_\_\_\_\_\_\_\_\_. Copy of informed consent template attached.

Confidentiality: