**RESEARCH INVOLVING ONLY RETROSPECTIVE CHART REVIEWS**

**INITIAL SUBMISSION FORM**

**Please ensure that all applicable materials listed below are submitted to the IRB office. The IRB will not put the research on an IRB agenda until all applicable materials listed below are received.**

\_\_\_\_\_\_\_\_\_\_\_\_ Protocol

\_\_\_\_\_\_\_\_\_\_\_\_ Data Collection Form

\_\_\_\_\_\_\_\_\_\_\_\_ Request for Waiver of Informed Consent (if applicable)

\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator Agreement

\_\_\_\_\_\_\_\_\_\_\_\_ Scientific Merit Review Form

\_\_\_\_\_\_\_\_\_\_\_\_ Nursing Research Council approval, if applicable

\_\_\_\_\_\_\_\_\_\_\_\_

SLHS INSTITUIONAL REVIEW BOARD

RETROSPECTIVE STUDY INITIAL SUBMISSION

1. **Administrative**

|  |  |
| --- | --- |
| Principal Investigator: |  |
| Email address: |  |
| Phone Number: |  |
| Number of studies principal investigator is currently conducting: |  |

|  |  |
| --- | --- |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining Consent from subjects? | [ ]  Yes [ ]  No |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining Consenting from subjects? | [ ]  Yes [ ]  No |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining Consent from subjects? | [ ]  Yes [ ]  No |
| Lead Study Coordinator: |  |
| Email Address: |  |
| Duties: |  |
| Obtaining Consent from subjects? | [ ] Yes [ ]  No |

|  |  |
| --- | --- |
| Other Study Staff:(List name, email address, duties of staff member and whether obtaining consenting from subjects) |  |
|  |
|  |
|  |
|  |

Source of Funding:

|  |
| --- |
| [ ]  Industry Sponsored Name of Sponsor: |
| [ ]  Federally funded |
| [ ]  Investigator Initiated Source of funding (if applicable): |
| If Investigator Initiated, select one: [ ]  Multi-site [ ]  Single Site |
| [ ]  Other |

1. **Location of the Study**
2. Check all SLHS facilities where research will take place:

[ ]  Saint Luke’s Hospital [ ]  Saint Luke’s South Hospital

[ ]  Saint Luke’s East Hospital [ ]  SLPS/SLMG physician practices

[ ]  Saint Luke’s North Hospital [ ]  SLCI Liberty

[ ]  Other SLHS affiliated site [ ]  Crittenton

[ ]  Inpatient setting [ ]  Outpatient setting

[ ]  Non-SLHS affiliated site \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Research Activity**
2. Does the research involve study of data, documents, records, pathological specimens or diagnostic specimens that are already in existence as of this date?

[ ]  Yes

[ ]  No *(NOTE: If you have selected NO, please stop and submit an application for prospective research)*

1. For what purpose were the data, records, specimens, etc. originally created?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What is the date range of records/specimens you wish to use?

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1. How many subjects do you plan to study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Check all that apply to the human subjects who will be enrolled in this study:

[ ]  Healthy volunteers [ ]  Pregnant Women

[ ]  Patients with a specific disease process [ ]  Terminally ill

[ ]  Children (18 yrs or less) [ ]  Fetuses/Neonates

[ ]  Prisoners [ ]  Cognitively impaired

[ ]  Homeless [ ]  SLHS employees

[ ]  Wards of the state/children in court custody [ ]  Patients with active psychiatric disease

[ ]  People unable to read, speak or understand English

[ ]  SLHS employees [ ]  Females only

[ ]  Males only

1. Will you record any subject identifiers or maintain a list that links the research data to the subject or subject’s records? Subject identifiers include, for example, a subjects’ name, medical record number, date of birth, social security number, etc.

[ ]  Yes

[ ]  No

If Yes, please explain why it is necessary to record identifiers or keep the linking list. \_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Are you seeking a waiver of informed consent?

[ ]  Yes *(NOTE: There is an additional form to complete)*

[ ]  No, I intend to obtain consent *(If no, please ensure your protocol outlines the consent process and provide a consent document for review)*

1. For medical record review, describe how the records to be reviewed will be identified and who will identify them.

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1. **Data Security**
2. Where will the data be stored?

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1. Who will have access to the data?

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1. Please explain how the data will be secured.

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1. Will study personnel electronically receive identifiable data or samples from an outside institution?

[ ]  No

[ ]  Yes

If yes, please describe the type of data, where it is coming from, and the plans for secure transmission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Do you plan on sharing the data with anyone outside of SLHS?

[ ]  No

[ ]  Yes

If yes, please explain with whom the data will be shared and what data points you intend to share. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Conflict of Interest**

*Prior to IRB approval, all personnel listed on the study must complete a financial conflict of interest disclosure. The questions below apply to the study on this application. The questions below apply to all members of the study team.*

1. Do any members of the study team or their immediate family members have a financial interest in the sponsoring company? *(This includes honoraria, income, stock/stock options)*

[ ]  YES

[ ]  NO

1. Do any members of the study team or their immediate family members have any consulting agreements, advisory positions or management responsibilities with the sponsoring company? *(this includes both paid and unpaid positions)*

[ ]  YES

[ ]  NO

1. Do any members of the study team or their immediate family members receive gift funds, educational grants or any other remuneration from the sponsoring company?

[ ]  YES

[ ]  NO

1. Do any members of the study team or their immediate family have any ownership or royalty interest in the intellectual property utilized in this study?

[ ]  YES

[ ]  NO

1. Have any members of the study team or their immediate family been reimbursed by this company for travel?

[ ]  YES

[ ]  NO

If you answered yes to any of the questions above, details must be provided to the IRB office prior to consideration of the submission.