**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?

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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. \_\_\_\_\_\_\_\_\_

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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.