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

**\_\_\_\_\_\_\_\_ Initial Submission Form**

**\_\_\_\_\_\_\_\_ Protocol**

**\_\_\_\_\_\_\_\_ Investigator’s Brochure**

**\_\_\_\_\_\_\_\_ Proposed Informed Consent Document**

**\_\_\_\_\_\_\_\_ Proposed Parental Permission Document**

**\_\_\_\_\_\_\_\_ Proposed Assent Document**

**\_\_\_\_\_\_\_\_ For Drug Studies, FDA letters (e.g. IND or IND exempt)**

**\_\_\_\_\_\_\_\_ For Device Studies, FDA letters (e.g. IDE or IDE exempt or Sig Risk or Non-sig Risk)**

**\_\_\_\_\_\_\_\_ For Device Studies, Device Manual, Instructions for Use**

**\_\_\_\_\_\_\_\_ Advertising and Recruitment Materials**

**\_\_\_\_\_\_\_\_ Scientific Merit Review form (Required for Investigator Initiated Studies)**

**\_\_\_\_\_\_\_\_ Data collection sheet**

**\_\_\_\_\_\_\_\_ DSMB or DMC charter or monitoring plan**

**\_\_\_\_\_\_\_\_ Radiation Safety approval**

**\_\_\_\_\_\_\_\_ IBC approval**

**\_\_\_\_\_\_\_\_ Nursing Research Council approval**

**\_\_\_\_\_\_\_\_ Informed Consent Waiver Request**

**\_\_\_\_\_\_\_\_ Informed Consent Documentation Waiver Request**

**\_\_\_\_\_\_\_\_ HIPAA Authorization Form or Waiver Request**

**\_\_\_\_\_\_\_\_ Surveys or other Instruments to be Used**

**\_\_\_\_\_\_\_\_ Subject Instructions, Diaries, Etc.**

**\_\_\_\_\_\_\_\_ Investigators’ CVs *(Please submit the most recent version of the CV at the time of initial submission for the Principal Investigator and all Sub-Investigators)***

**\_\_\_\_\_\_\_ Proof of Completion of Required Training *(Please submit the certificate of completion for CITI training for each person listed on the study)***

SLHS INSTITUIONAL REVIEW BOARD

INITIAL REVIEW SUBMISSION

1. **Administrative**

|  |  |
| --- | --- |
| Principal Investigator: |  |
| Email address: |  |
| Phone Number: |  |
| Number of studies principal investigator is currently conducting (i.e. listed as PI): |  |

|  |  |
| --- | --- |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining consent? | Yes  No |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining consent? | Yes  No |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining consent? | Yes  No |
| Sub-Investigator(s): |  |
| Email address: |  |
| Duties: |  |
| Obtaining consent? | Yes  No |
| Lead Study Coordinator: |  |
| Email Address: |  |
| Duties: |  |
| Obtaining consent? | Yes  No |
| Other Coordinators (list email addresses and whether obtaining consent): |  |
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| --- | --- |
| Other Study Staff:  (List name, email address, duties of staff member and whether obtaining consent) |  |
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Federally regulated:

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| --- |
| FDA regulated |
| IND # |
| IDE # |

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. Is this is a multi site study for which you are the lead investigator or SLHS is the lead site or coordinating center?

No  Yes

If yes, please list the other planned locations: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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***\*\*If yes, please contact the IRB office prior to submitting your study for further instructions***

1. Check all SLHS facilities where research will take place:

Saint Luke’s Hospital  Saint Luke’s South Hospital

Saint Luke’s East Hospital  SLCC/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. **Subject Selection, Recruitment and Compensation**
2. Number of patients to be enrolled at SLHS sites: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Age Range of patients to be enrolled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Check all that apply to the human subjects who will be enrolled in this study:

Healthy volunteers  Pregnant Women/Fetuses

SLHS Patients with specific disease process  Terminally ill

Children (18 yrs or less)  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

Males only  Females only

1. If vulnerable populations are selected above (i.e. children, prisoners, pregnant women, cognitively impaired, etc.) please describe special protections being put in place, for example, to minimize risk of coercion or undue influence, assessment of cognitive status, use of surrogate decision makers and/or assent.

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1. How will subjects be recruited? Check all that apply

Identification during course of usual clinical care  Flyer, ad or website

Chart review by persons involved in patients’ care  Mailers

Chart review by persons not involved in patients’ care  Referrals from other physicians

Database searches  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. Will subjects be compensated for their participation?

Yes Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No

1. If funded, has the contract, budget and consent form been reviewed by the Manager of Research Business Operations?

Yes  No

\*\*For clarification or questions, please contact Anne Hoffman at 816-932-3623 or ahoffman@saint-lukes.org

1. **Study Value, Validity, and Design**

What is the scientific value of the research? (In other words, why is the research needed?)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is the study designed to be scientifically valid?

Yes

No

1. Is the selection of study subjects equitable? Is the selection of study subjects appropriate to meet the study objectives? (Also comment, if appropriate, on the inclusion/exclusion criteria.)

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

1. What is the standard of care in the subject population being studied?

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1. Why is the current standard of care not sufficient to meet treatment goals?

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1. Describe how the research procedures/treatment differ from the standard of care.

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1. **Risk/Benefit Information**
2. Please describe the serious or common risks related to the research intervention (consider physical, psychological, economic, social, and legal risks).

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1. How are the risks listed in (a) minimized?

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1. Describe how are the risks to subjects reasonable in relation to the potential benefits.

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1. **Consent Process**
2. Will you use a written informed consent document?

Yes

No, I am seeking a waiver of documentation of informed consent *(NOTE: there is an additional form to complete)*

No, I am seeking a waiver of informed consent *(NOTE: there is an additional form to complete)(NOTE: you cannot waive informed consent for FDA-regulated research)*

No, I am seeking a waiver of parental permission *(NOTE: there is an additional form to complete) (NOTE: you cannot waive parental permission for FDA-regulated research)*

1. Will subjects have sufficient time to consider whether or not to join the study?

Subjects will be allowed to take home the unsigned consent form for consideration prior to reviewing it with study personnel for an in-person consent discussion

Subjects will be allowed a waiting period of at least \_\_\_\_\_\_ hours to consider their decision

For medical or scientific reasons, a waiting period is not appropriate.

Other

1. Where will the consent process occur?

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

1. Do you anticipate enrolling subjects whose primary language is not English?

No

Yes

If yes, how will you obtain informed consent in a language understandable to those subjects?

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1. Do you anticipate enrolling adult subjects who are unable to provide consent for themselves?

No

Yes

If yes, how will study personnel assess the capacity of each subject to provide consent?

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

If yes, do you have a process for having a legally authorized representative sign the consent document?

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If yes, can the subjects provide assent?

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1. For studies involving children, do you plan to obtain assent from the child?

Yes

No

N/A

1. If you answered yes to (f), what is the age range of the children from whom you will obtain assent?

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1. How do you propose to document the child’s assent?

N/A

By obtaining the child’s signature on a written assent form

By documenting the child’s verbal assent in the clinical record

Other

1. Will any of the children enrolled be foster children or wards of the state?

No

Yes

*\*\*If yes, please contact the IRB office for guidance prior to submitting your study for review. Additional requirements may apply.*

1. **Privacy and Confidentiality**
2. Do you intend to collect and record identifiable information about subjects?

Yes

No

1. What measures will you take to protect subject privacy?

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1. Where will the subjects’ information be stored?

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1. Who will have access to the subjects’ identifiable information?

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1. If data will be stored electronically or in hard copy, where will it be stored and what is the plan for ensuring protection of that data?

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1. **Study Procedures**

From the list below, please check the procedures that will be part of your research.

1. Use of Radiation or a Radioisotope  Yes  No

*\*\*If you answer yes, please note you must complete the Radiation Safety form*

1. Genetic Testing  Yes  No
2. Storage of human biological materials for purposes not related  Yes  No

to this project (future research)

1. Audio taping or videotaping  Yes  No
2. Investigational surgical procedure  Yes  No
3. Testing for illegal drug use?  Yes  No
4. Collection of information related to physical or psychological abuse?  Yes  No
5. Collection of information related to criminal behavior?  Yes  No
6. **Safety Monitoring**
7. What type of safety monitoring are you proposing for this study?

Data Safety Monitoring Board

Investigator or study team monitoring plan *(if selecting this option, the safety monitoring plan must be included in the protocol or as an attachment to the IRB submission)*

Other monitor or monitoring entity

1. What will be the frequency of the monitoring?

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1. What types of safety related events would cause the sponsor or investigator to stop or suspend the study?

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1. **Drugs and Devices**

**Drugs or Biologics:**  **N/A**

1. The drugs/biologics to be used in the trial are:

FDA approved and used in accordance with its approved labeling for the proposed the research

Not FDA approved for marketing (i.e. investigational)

FDA approved but not being used in accordance with its approved labeling for the proposed research (i.e. investigational)

There is an IND for the drug/biologic to be used in the trial. IND number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: You must submit letter from FDA (e.g. IND or IND exempt letter)

1. Has the FDA required a black box warning for a drug/biologic used in this study?

Yes

No

If yes, specify the reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, what will be done to address these risks? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Where will the drugs/biologics be dispensed?

At study visit

At patient’s home

Other

1. Who will be administering the drug/biologic? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Where will the drugs/biologics be stored?

Investigational Pharmacy

Physician office

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Where will the drug/biologic be shipped?

Investigational pharmacy

Investigator’s office

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Devices:**  **N/A**

1. The devices used in the research are:

FDA approved and used in accordance with its approved labeling for the proposed research

Not FDA approved or cleared for marketing (i.e. investigational)

FDA approved but not being used in accordance with its approved or cleared labeling for the proposed research (i.e. investigational)

IDE has been issued by FDA. IDE Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FDA has issued a significant or non significant risk determination

The sponsor has made a significant or non significant risk determination

This device is IDE exempt(NOTE: You are required to submit any applicable letter from FDA (e.g. IDE or IDE exempt)

1. Where will the investigational device be stored? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. What is your plan for control and handling of study devices? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. How have investigators and study team been trained on the use of the device? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **Conflict of Interest**

*Prior to IRB approval, all personnel listed on the study must complete a financial interest disclosure. This document will be reviewed to assess conflicts of interest. The questions below apply to this particular research. 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.

**REQUIRED SIGNATURES**

Will any residents, fellows or students be involved in the research proposed in this application? If yes, you must obtain the signature of the Director of Medical Education. Please list the names of those individuals and whether they are residents, fellows or students.  N/A

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Director of Medical Education Signature Date

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

Principal Investigator Signature Date

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

Department Director Name

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

Department Director Signature Date