

Institutional Review Committee

This document should be a description of the proposed research. “Refer to Protocol” or “Refer to Informed Consent Document” **WILL NOT** be acceptable answers. **ALL** items must be answered.

General Information

1. Title of Study

2. Sponsor of Study:

<input type="checkbox"/> Investigator-Initiated	<input type="checkbox"/> Federal Agency/CO-OP Oncology Group
<input type="checkbox"/> Commercial Sponsor (<i>specify</i>)	<input type="checkbox"/> Other (<i>specify</i>)

3. Investigators:	Name	Degree(s)	Affiliation/Practice Name
Primary Investigator*			
Sub/Co-Investigator			

*Either the Primary Investigator or a Sub/Co-Investigator must have a formal affiliation with the facility where the research will be done.

If the Primary Investigator is a resident or trainee, the Co-Investigator must have a formal affiliation with the facility where the research will be done.

4. Do the Investigators participating in this study have clinical privileges to perform the procedures described in the Protocol at Mercy Medical Center or Mercy Capitol? Yes No

If **“No”**, describe how they will obtain necessary training or certification to carry out the procedures

5. Have all Investigators received training in Human Subjects Training? Yes No

If **“No”**, describe how and when they will obtain appropriate training

6. Purpose (objective) of the Study:

7. Scientific rationale for Study:

Clinical Trial Information

1. Study Design (i.e. open-label, rct, placebo-controlled, etc.)

Clinical Protocols Only: Pilot Phase 1 Phase 2 Phase 3 Phase 4

2. Methods or Procedures:	
3. Inclusion Criteria:	
4. Exclusion Criteria:	
5. List all test articles, approved drug, study drug, or device that will be used in this trial.	
6. Is your test article investigational?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
7. Indicate the FDA IND or IDE number: # _____ <input type="checkbox"/> NA If there is no IND or IDE number, please explain why:	
8. If a device is involved, has it been designated by the Study Sponsor as a NSR? (non-significant risk)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
9. Is any medicine or device, used in this study, classified with an HDE, HVE, or other exemption?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
If YES , identify and explain. ****Attach any documentation granting such exemption	
10. Duration of the study: _____ years	Duration for individual subjects:
11. Will recruitment of subjects for this protocol conflict with recruitment for any other approved protocol that you or your colleagues are pursuing?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
12. Number of subjects expected to be enrolled at this site:	At all sites:
13. Data or samples to be collected:	
14. Will the protocol be audited or monitored at this site? If YES , by whom?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Resources Needed for the Protocol	
1. Does this protocol require access to equipment or other resources not normally available to the investigator? If YES , describe what arrangements will be made to acquire the necessary resources.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2. Does this protocol require that the investigator or any	

<p>member of the research team receive additional or specialized training? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, describe what arrangements will be made to acquire the necessary training.</p>
<p>3. Does this protocol require a time commitment from the Principal Investigator that might necessitate decreasing time devoted to clinical practice or other professional activities? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, please explain why:</p>
Technological Resources to be Used with the Protocol
<p>1. Will the trial be using an electronic version of the case report forms? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p>
<p>2. Does the sponsor use a process to ensure that study information is securely transmitted over the Internet? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, please explain process:</p>
<p>3. Will information about this trial be posted on any website hosted by the sponsor or the site? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, please provide copy of information to be posted on the website and the website address:</p>
<p>4. Will any advertising for recruitment be used with this protocol either verbally, written or visual? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, please attach a copy of proposed advertising</p>
<p>5. Will there be any additional technological tools used for patient recruitment or information guides? (i.e. CD's, DVD's, VHS tapes, etc.) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>If YES, please describe:</p>
Risk/Benefit Considerations
<p>1. List potential benefits to subject:</p>
<p>2. List potential benefits to others:</p>
<p>3. List potential or real risks to subjects:</p>
<p>4. Does participating in this protocol present any unusual risks to the confidentiality of subjects' medical information? (i.e. history of drug use, HIV/AIDS, testing/status, genetic testing, etc.) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p>
<p>5. Please write an assessment of the risk/benefit ratio:</p>

Justice	
<p>1. Does subject population include fetuses, pregnant women, children, the mentally disabled, prisoners, or any other subjects whose ability to give voluntary and informed consent may be in questions? If YES, briefly discuss the rationale for utilizing this population:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
<p>2. Will the subjects be recruited from a population that normally has access to standard medical care for the condition being studied in this Protocol? If NO, what is the rational for recruiting subjects from this population?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
<p>3. Will language or translation issues be involved in obtaining consent? If YES, briefly discuss the methods in place to address this issue:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Financial Considerations – Research Participant	
<p>1. Please fill out the attached Billing & Allocation Guideline form (Addendum A)</p>	
<p>2. In the event of a research related injury, will the sponsor(s) pay for medical care and/or hospitalization beyond what insurance doesn't cover?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
<p>3. Will the subject receive anything material for participation in the protocol? (i.e. calendars, bags, mugs, etc.) If YES, please explain:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
<p>4. Will the subject receive any monetary payment for participation or reimbursement for personal expenses in this protocol? If YES, please explain:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Financial Considerations – Investigator	
<p>1. Please have each investigator sign a Financial Disclosure for this submission (Addendum B)</p>	

Being Primary Investigator of the study being submitted, I certify that this application is complete and correct. I understand that federal regulations require Investigators to provide

periodic reports to the IRC including, but not limited to, any changes in the Protocol or Informed Consent or any unanticipated problems or adverse experiences involving risks to subjects or others. I further state that I am aware of the institutional, local, state, and federal laws and regulations governing human research subjects. I certify that I and all other persons involved in the administration of this Study will abide by all applicable laws and regulations and that each person has had the appropriate training to insure compliance with these requirements.

Signature of Principal Investigator

Date

Signature of Co-Investigator

Date

Required Submission Documents

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| 1. Completed and signed (original signature) IRC application** | <input type="checkbox"/> Attached |
| 2. Site specific patient informed consent form** | <input type="checkbox"/> Attached |
| 3. Protocol or study design** | <input type="checkbox"/> Attached |
| 4. Investigator's Brochure and/or Instruction for Use** | <input type="checkbox"/> Attached |
| 5. Billing & Allocation Guideline** | <input type="checkbox"/> Attached |
| 6. Financial Disclosure form for each investigator on application** | <input type="checkbox"/> Attached |
| 7. Grant Application | <input type="checkbox"/> Attached <input type="checkbox"/> NA |
| 8. HDE, HVE, or other exemption letters | <input type="checkbox"/> Attached <input type="checkbox"/> NA |
| 9. Recruitment materials including advertisements intended to be seen, heard, or read by potential participants.
(This includes website information) | <input type="checkbox"/> Attached <input type="checkbox"/> NA |
| 10. CV for every investigator listed on application.
(Only needs to be submitted once every calendar year) | <input type="checkbox"/> Attached <input type="checkbox"/> NA |

****Indicates required documentation for submission**