

Mercy Medical Center – Des Moines Institutional Review Board

Research Application

Preparing the Application

1. Please submit a typewritten and completed application with appropriate documentation.
2. “Refer to Protocol” or “Refer to Informed Consent Document” will not be acceptable answers. All items must be answered.
3. Either the Primary Investigator or a Sub-Investigator must have a formal affiliation with the facility. If the Primary Investigator is a resident or trainee, the Co-Investigator must have a formal affiliation with the facility where the research is done.
4. **ALL** Investigators listed on the application **ARE REQUIRED** to have Human Research Protection Training completed. If the investigator has not completed this training by the submission of the application, the investigator **CAN NOT** be listed on the application.
5. All required documentation listed in Section 8 needs to be submitted with the completed application.
6. This application will not be processed if not completed. This could result in the application being delayed.

To move through this document, please keep document “locked” and use “Tab” key.

Please forward documents
Mercy Medical Center – Des Moines
Institutional Review Board
1111 6th Avenue
Des Moines, IA 50314
(515) 247-3985 (office)
(515) 643-8986 (fax)
mwhite3@mercydesmoines.org



Institutional Review Board
Research Application

1. Project Information

PLEASE PROVIDE ALL REQUESTED INFORMATION

Principal Investigator: _____

Site: _____

Name of Study: (Full Title) _____

Sub-Investigator	_____	Sub-Investigator:	_____
Sub-Investigator	_____	Sub-Investigator	_____
Sub-Investigator	_____	Sub-Investigator	_____
Sub-Investigator	_____	Sub-Investigator	_____
Sub-Investigator	_____	Sub-Investigator	_____
Sub-Investigator	_____	Sub-Investigator	_____

Do all Investigators participating in this trial have privileges to perform the procedures described in the protocol at Mercy Medical Center or any of its affiliates? Yes No

Have all Investigators received training in Human Research Protection Training? Yes No

2. Clinical Trial Information

PLEASE PROVIDE ALL REQUESTED INFORMATION

1.	Is this study for a <input type="checkbox"/> drug (example: insulin, cholesterol lowering, inhibitor, etc.) <input type="checkbox"/> device (example: stent, ear tube, injection pen, etc.)												
<i>If "device" is marked the completion of section #7 is required.</i>													
2.	This study is sponsored by: (check only one) <table style="float: right; border: none;"> <tr><td><input type="checkbox"/></td><td>Commercial Sponsored (specify):</td></tr> <tr><td><input type="checkbox"/></td><td>Investigator-Initiated</td></tr> <tr><td><input type="checkbox"/></td><td>NIH</td></tr> <tr><td><input type="checkbox"/></td><td>Other:</td></tr> </table>	<input type="checkbox"/>	Commercial Sponsored (specify):	<input type="checkbox"/>	Investigator-Initiated	<input type="checkbox"/>	NIH	<input type="checkbox"/>	Other:				
<input type="checkbox"/>	Commercial Sponsored (specify):												
<input type="checkbox"/>	Investigator-Initiated												
<input type="checkbox"/>	NIH												
<input type="checkbox"/>	Other:												
3.	The phase of this trial is: <table style="float: right; border: none;"> <tr><td><input type="checkbox"/></td><td>Pilot</td><td><input type="checkbox"/></td><td>Phase 3</td></tr> <tr><td><input type="checkbox"/></td><td>Phase 1</td><td><input type="checkbox"/></td><td>Phase 4</td></tr> <tr><td><input type="checkbox"/></td><td>Phase 2</td><td><input type="checkbox"/></td><td>N/A</td></tr> </table>	<input type="checkbox"/>	Pilot	<input type="checkbox"/>	Phase 3	<input type="checkbox"/>	Phase 1	<input type="checkbox"/>	Phase 4	<input type="checkbox"/>	Phase 2	<input type="checkbox"/>	N/A
<input type="checkbox"/>	Pilot	<input type="checkbox"/>	Phase 3										
<input type="checkbox"/>	Phase 1	<input type="checkbox"/>	Phase 4										
<input type="checkbox"/>	Phase 2	<input type="checkbox"/>	N/A										
4.	Indicate the FDA IND or IDE Number <input type="checkbox"/> N/A												
5.	State purpose of this trial												
6.	Indicate the scientific rationale for this trial												
7.	Give a summary of any previous animal or human clinical trial results.												
8.	Summarize methods or procedures for this trial												
9.	List the inclusion criteria												
10.	List the exclusion criteria												
11.	List all test articles, test drugs, and approved drugs to be used in this trial												
12.	Summarize data or samples to be collected												
13.	Duration of the study _____ Duration for individual subjects _____												
14.	Number of subjects expected to be enrolled at this site _____ Number of subjects expected to be enrolled study wide _____												

		Yes	No	N/A
15.	Is your drug or device investigational?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	If a device is involved, has it been designated by the Study Sponsor as a NSR? (non-significant risk)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	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"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Will the protocol be audited or monitored at this site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Resources and Technological Resources Used for Protocol

PLEASE PROVIDE ALL REQUESTED INFORMATION

		Yes	No	N/A
19.	Does this protocol require access to equipment or other resources not normally available to the investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20.	Does this protocol require that the investigator or any member of the research team receive additional or specialized training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21.	Does this protocol require a time commitment from the Primary Investigator that might necessitate decreasing time devoted to clinical practice or other professional activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22.	Will the trial be using an electronic version of the case report forms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23.	Does the sponsor use a process to ensure that the study information is securely transmitted over the Internet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24.	Will information about this trial be posed on any website (other than clinicaltrials.gov) hosted by the sponsor or the PI's site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25.	Will any advertising for recruitment be used with this protocol either verbally, written or visual?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.	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"/>	<input type="checkbox"/>	<input type="checkbox"/>
27.	Please give a short summary for any questions marked as, "Yes"			

4. Risk/Benefit Considerations

PLEASE PROVIDE ALL REQUESTED INFORMATION

28.	State potential or real risks to subjects		
29.	State potential benefits to subjects or the public in general		
30.	Please give an assessment of the risk/benefit ratio		
31.	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, genetic testing, etc.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
32.	If question #31 is "Yes" please give a short summary of the unusual risks to the confidentiality of the subject's medical information. <input type="checkbox"/> N/A		

5. Justice

PLEASE PROVIDE ALL REQUESTED INFORMATION

		Yes	No	N/A
33.	Does the subject population for this trial include fetuses, pregnant women, children, mentally disabled, prisoners, non-English speaking subjects or any other subject that could be considered a vulnerable population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34.	Will subjects be recruited from a population that normally has access to standard medical care for the condition being studied in this protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35.	Will language or translation issues be involved in obtaining consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36.	If question #33 or #35 is "Yes" please give a brief explanation <input type="checkbox"/> N/A			

6. Financial Considerations of Subjects

PLEASE PROVIDE ALL REQUESTED INFORMATION

		Yes	No	N/A
37.	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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38.	Will subjects receive anything material for their participation? (calendars, bags, mugs, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39.	Will the subject receive any monetary payment or reimbursement for personal expenses for their participation in this trial?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40.	If question #38 or #39 is "Yes" please give a brief explanation <input type="checkbox"/> N/A			

7. Medicare Reimbursement Agreement

Investigational Device Exemption (Category B) Submission Requirements

The following items must be submitted by the providing hospital for local approval by CMS' regional MAC claims administrator's Medical Director for all Investigational Devices (for which CMS may be billed) after receiving the Institutional Review Board's approval and prior to beginning enrolling patients:

- A signed copy of the final FDA approval letter demonstrating Category B IDE status and approval from the FDA to the participating company or manufacturer.
- IDE device number
- Number of patients to be enrolled at your institution
- A summary description of the device
- A copy of the protocol you intend to follow when performing the procedure utilizing the Category B IDE device
- A copy of the agreement between the company or manufacturer and the provider, furnishing the details of provider participation in the study.
- Any product literature illustrating the device and/or the procedure
- A list of any alternative devices, therapies, etc, that may be available to treat the indicated disease.
- A copy of the protocol used for obtaining informed consent from beneficiaries for their participation in the study.
- An institutional review Board/board approval letter or statement from the provider assuring the approval has been obtained from the study institution
- Any changes to the submitted information (including a change in providers) should be forwarded to the MAC as soon as possible

As the Primary Investigator, I agree that our site will not enroll any subjects into this investigational device exemption trial until Mercy Medical Center – Des Moines has received approval from the local CMS regional MAC Medical Director for subject reimbursement. I understand that Mercy will notify either myself or my designee of local CMS regional approval once it has been obtained.

Primary Investigator Signature

Date

8. Signature

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 IRB 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 Sub-Investigator

(only to be signed if PI is not available at time of submission)

Date

9. Required Documentation for Submission

		Attached	N/A
1.	Completed and signed (original signature) IRB application	<input type="checkbox"/>	<input type="checkbox"/>
2.	Site specific Patient Informed Consent form	<input type="checkbox"/>	<input type="checkbox"/>
3.	Protocol	<input type="checkbox"/>	<input type="checkbox"/>
4.	Investigator's Drug Brochure or Instructions for Use	<input type="checkbox"/>	<input type="checkbox"/>
5.	Billing and Allocation Guideline	<input type="checkbox"/>	<input type="checkbox"/>
6.	Financial Disclosure for each investigator listed on application	<input type="checkbox"/>	<input type="checkbox"/>
7.	IRB Fees Invoice Information Sheet	<input type="checkbox"/>	<input type="checkbox"/>
8.	A copy of the investigator's Human Research Protection Training certificate (if not previously filed in the IRB office)	<input type="checkbox"/>	<input type="checkbox"/>
9.	CV for every investigator listed on application (only needs to be submitted once every calendar year)	<input type="checkbox"/>	<input type="checkbox"/>
10.	Recruitment materials including advertisements intended to be seen, heard, or read by potential subjects. (this includes website information)	<input type="checkbox"/>	<input type="checkbox"/>

**MERCY MEDICAL CENTER – DM
 Institutional Review Board
 Clinical Research Protocols**

Billing and Allocation Guideline for Patient Account

Protocol Name: _____

Sponsor: _____

Principal Investigator: _____

Approval Date: _____

Inpatient Costs Paid by Research Sponsor (Include Test Device, Article #)	Inpatient Patient/Insurance Billable (Standard of Care Related)
Outpatient Costs Paid by Research Sponsor (Include Test Device, Article #)	Outpatient Patient/Insurance Billable (Standard of Care Related)

Research Coordinator/Director Name (Print) _____

Signature: _____

Phone: _____



Mercy Medical Center Institutional Review Board
Significant Financial Interests in a Sponsored Project

The purpose of this document is to assist in the determination of whether additional restrictions, oversight, or other condition as might be advisable prior to the Mercy Medical Center Institutional Review Board approval of a proposed research project. Disclosure forms are to be forward with your application of your proposed project.

Yes No Do you personally have an ownership interest in the sponsor of the proposed project consisting of: (a) stock with a current market value of more than \$10,000 or (b) more than 1% of the equity of the company (in those cases in which a company is not listed on a stock exchange)? (**DO NOT** report holdings in mutual funds or TIAA/CREF).

Yes No Do you, your spouse, and your dependents, in the aggregate, have any ownership interests (stock, stock options, and/or any debt, security or capital holding) that have a current market value of \$10,000 or more or that represents 5% or more of the total equity in any outside entity related to the proposed sponsored project? (**DO NOT** report holdings in mutual funds or TIAA/CREF). Any entity related to the propose sponsored project would include any:

- Supplier of equipment, materials, or services related to the research,
- Business commercializing a product that the research is intended to evaluate or further develop, or
- Party whose financial interests would seem to be directly and significantly affected by the research.

Yes No Are you an employee, officer, or director in the sponsor of the proposed project?

Yes No Do you, your spouse, and your dependents, in the aggregate, receive salary or other remuneration or financial considerations equal to or more than \$10,000 per year as an employee, consultant, officer, or board member of any entity related to the propose project?

An entity related to the propose project includes any:

- Supplier of equipment, materials, or services related to the research,
- Business commercializing a product that the research is intended to evaluate or further develop, or
- Party whose financial interests would seem to be directly and significantly affected by the research.

If you answered “YES” to any of the above questions, please specify:

Signature: _____ Date: _____

Mercy Medical Center - Institutional Review Board
Billing Information for Mercy IRB Fee

Bill IRB fees the Sponsor Information Listed Below:

Sponsor Contact: _____

Contact Address: _____

Contact Phone: _____ Fax: _____

Contact E-mail: _____

Bill IRB fees to the research site because one of the following is true:

- The IRB fee was included in the sites "start-up pay"
- The Clinical Trial Agreement states that fees will be paid by the Investigator's Site
- The IRB fee was pre-paid to the Investigator's site

Please waive all IRB fees because (check all that apply)

- NIH trial
- Investigator Initiated
- Study is funded by a private grant

**All submitted applications will be invoiced approximately one week after it is reviewed at a fully convened IRB meeting. This fee is for review of the application, protocol and all other supporting documentation. It is not for approval. All invoices will be due within 45 days of the date of signature on certified mail documentation. Should the invoice not be paid within 45 days, it is a possibility that the study may be placed on Administrative Hold. This means that any other submissions will not be processed through the IRB office until payment is received. The only exception would be any safety issues.

**PLEASE NOTE: If a contract between the site and the sponsor is not signed at the time of submission of the application, and an agreement is not reached, the site will be billed \$1,000 for the IRB review and processing fees.