

Mercy Medical Center – Des Moines Institutional Review Board

Amendment Application

Preparing Amendment Application

1. Federal Regulations require that the IRB be notified of, and grant prior approval for, any proposed changes in approved research.
2. Please submit a typewritten and completed application with appropriate documentation.
3. If submitting a Full Board Review Amendment, a summary of changes is required from either the sponsor or the investigator.
4. If adding new investigators, Human Research Protection Training **must** be completed before request can be submitted.
5. This application will not be processed if not completed. This could result in the amendment review 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)
dburns@mercydesmoines.org

1. Project Information

PLEASE PROVIDE ALL REQUESTED INFORMATION

Principal Investigator: _____

Site: _____

Name of Study: _____

Mercy IRB #: _____

2. Type of Modification (Expedited Review)

CHECK ALL THAT APPLY

<input type="checkbox"/>	Change in Research Site	<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Change in Subject Enrollment	<input type="checkbox"/> Increase by: _____ <input type="checkbox"/> Decrease by: _____ Resulting Total to be Enrolled: _____	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Change in Study Personnel	<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify If adding new personnel – Complete Section #4	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Other Change	Specify Type: _____	<input type="checkbox"/> ICF Change*

If available, attach the sponsor correspondence that is requesting this revision. Otherwise, give a brief Narrative Summary of proposed modifications.

***ATTACH THE PROPOSED ICF WITH CHANGES TRACKED ONLY IF ONE OF THE ABOVE ACTIONS AFFECTS THE ICF**

3. Type of Modification (Full Board Review)

CHECK ALL THAT APPLY

<input type="checkbox"/>	Industry or Multi-Site Protocol Amendment	Amendment # _____ Dated: _____ ATTACH COPY OF REVISED RESEARCH METHODS/RESEARCH PLAN OR PROTOCOL, AS APPLICABLE	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Industry or Multi-Site Amendment to IDB/IFU	Version #: _____ Dated: _____ ATTACH COPY OF REVISED INVESTIGATOR'S DRUG BROCHURE OR INSTRUCTIONS FOR FOLLOW-UP, AS APPLICABLE	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Revised Drug Package Insert	Version #: _____ Dated: _____	<input type="checkbox"/> ICF Change*
<input type="checkbox"/>	Other Change	Specify Type: _____	<input type="checkbox"/> ICF Change*
<p>If available, attach the sponsor correspondence that is requesting this revision. Otherwise, give a brief Narrative Summary of proposed modifications.</p>			

***ATTACH THE PROPOSED ICF WITH CHANGES TRACKED ONLY IF ONE OF THE ABOVE ACTIONS AFFECTS THE ICF**

4. Addition of New Sub-Investigator(s)

Name	Degree	Role In Study	Date HSP Complete

PLEASE ATTACH:

- An original signed and dated Financial Disclosure Form
- A copy of the Human Subject Protection Training Certificate (if not previously filed in IRB office)
- An original signed and dated CV (if not previously filed in the IRB office for this calendar year)

I acknowledge my role in this research study, and agree to the policies and procedures of Mercy Medical Center – Des Moines and the Mercy Medical Center Institutional Review Board for the protection of human subjects participating in research.

Signature of Sub-Investigator

Date

Signature of Sub-Investigator

Date

Signature of Sub-Investigator

Date

5. Signature of Primary Investigator

I am submitting this form in accordance with the policies of the Mercy Medical Center – Des Moines Institutional Review Board. I understand that I cannot initiate any changes in my approved protocol before I have received approval (expedited or full board review) and/or complied with all contingencies made in connection with that approval.

Upon approval by the IRB, this Modification/Amendment will, along with all existing approved materials, constitute a full and accurate description of the research study I am conducting.

Signature of Primary Investigator

Date

Please submit original application to the Mercy Medical Center IRB Office