

Mercy Medical Center – Des Moines Institutional Review Committee

Waiver of Consent Application

Preparing Waiver of Consent Application

1. Please submit a typewritten and completed application.
2. If the Primary Investigator is a resident or trainee in a program sponsored by a constituent entity of Mercy Medical Center then this application must be sponsored by a Program Director or Faculty Member who will be held to the same Assurances as the Primary Investigator. Please list the Faculty Sponsor as a Sub-Investigator.
3. Waiving informed consent for research must satisfy **ALL** of the conditions listed in the Federal regulations for Protection of Human Subjects, 45 CFR 46, and Standard for Privacy of Individually Identifiable Health Information (a.k.a. HIPAA), 45 CFR 164.512. These conditions are:
 - a. The research involves no more than minimal risk to the subjects;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration; and
 - d. *Whenever appropriate*, the subjects will be provided with additional pertinent information after participation.
4. Anyone listed on this application is required by Federal Regulations and IRC policy to have completed Human Research Protection Training. This can be obtained through the NIH or CITI website, PRIM&R 101 or 250, or VA Medical Training.
5. This application will not be processed if not completed. This could result in your trial being tabled.

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

Please forward documents
Mercy Medical Center – Des Moines
Institutional Review Committee
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Des Moines, IA 50314
(515) 247-3985 (office)
(515) 643-8986 (fax)
dburns@mercydesmoines.org



Institutional Review Committee
Waiver of Consent Application

1. Project Information

PLEASE PROVIDE ALL REQUESTED INFORMATION

Principal Investigator: _____

Site: _____

Name of Study: (Full Title) _____

Primary 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. Data Collection

CHECK ALL THAT APPLY

Please mark all boxes of information that will be collected as part of the study data.

<input type="checkbox"/>	Name	<input type="checkbox"/>	Telephone Number
<input type="checkbox"/>	Social Security Number	<input type="checkbox"/>	Account Numbers
<input type="checkbox"/>	Fax Numbers	<input type="checkbox"/>	Medical Record Numbers
<input type="checkbox"/>	Full face photographic images	<input type="checkbox"/>	Date of Birth
<input type="checkbox"/>	Health plan beneficiary numbers	<input type="checkbox"/>	Other (<i>specify</i>):

3. Regulation Requirements

PLEASE PROVIDE ALL REQUESTED INFORMATION

1.	State why the research involves no more than minimal risk to the participants
2.	State why the waiver or alteration will not adversely affect the rights or welfare of the participants.
3.	State why the research could not practicably be carried out without the waiver

4. Protection of Patient Identifiers

PLEASE PROVIDE ALL REQUESTED INFORMATION

4.	Summarize the plan to protect identifiers from improper use and disclosure
5.	Summarize the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or is otherwise required by law.
6.	Summarize the written assurances that PHI (Personal Health Information) will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project.
7.	Summarize how the identifiers will be destroyed.

5. Signatures

I certify that this protocol is being conducted in adherence to the FDA, DHHS, OHRP and Mercy Medical Center – Des Moines IRC policies for the protection of the rights and welfare of human participants in research.

I certify that the above information is accurate. I certify that all study personnel will comply with HIPAA regulations, that the protected health information requested is the minimum necessary to meet the research objectives, and that the protected health information I obtain as part of this research will not be reused or disclosed to any other person other than the study personnel, except as required by the law.

I also agree to notify the IRC in writing if there is any change in the above information.

Primary Investigator Name (Printed)

Primary Investigator Signature

Date