

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: HSRC
	SUBJECT	Initial Application
	SOP #	3.1
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	October 17, 2017

OBJECTIVE

Describe the required procedures to submit an application to the Human Subject Research Committee. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Protection of Human Subjects
21 CFR 50 Protection of Human Subjects
21 CFR 56 Institutional Review Boards
21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
HHRI Sponsored Project Administration: Guidance and Procedures
HCMC Research Resource Approval Process: <https://infooncall/Systems/Research/index.htm>

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.2
SOP 2.9
SOP 2.10

ATTACHMENTS

None

- 1) For information, questions, concerns, or suggestions concerning the Human Subjects Research Protection Program (HSRPP) please contact the Office for Human Subjects Research (OHSR) at:
 - a) 612-873-6881
 - b) <https://hhrinstitute.org/office-of-research-services/irb-office-for-human-subjects-research/>

- 2) To obtain the latest version of the Human Subjects Research Committee (HSRC) application contact:
 - a) 612-873-6881
 - b) <https://hhrinstitute.org/office-of-research-services/irb-office-for-human-subjects-research/>

- 3) To submit to the HSRC, complete the submission form per HSRC instructions.
 - a) Consider the probability of the category of review (full, expedited, or exempt review) and use the appropriate application form.
 - b) Base the decision for review on the scope of the trial, targeted subject population, criteria listed on application forms, and required study procedures.
 - c) Contact the OHSR or the Office for Education and Quality in Clinical Research (OEQCR)) for guidance.
 - d) The OHSR will make the final determination or required review.

- 4) HCMC informed consents must be formatted on grey edged HCMC consent paper titled “Consent for Clinical Investigations Conducted with Patients”.
 - a) Consent paper available in HCMC Storeroom.
 - b) If using an informed consent template provided by a sponsor, reformat it to the HSRC format using HSRC required wording.
 - c) Submit the reformatted consent to the sponsor for review if required.
 - d) Complete the HCMC Research Utilization Worksheet and submit it with the HSRC submission.
- 5) The PI or delegated individual will present the study to the HSRC.
- 6) Make the appropriate changes to the application/consent as outlined by the HSRC.
 - a) Send a revised informed consent to the sponsor for review if required.
 - b) Ensure that you receive a full approval letter from the HSRC with an approved informed consent document prior to beginning any research activities.
 - c) Keep a copy of the application, approved informed consent document, and all HSRC correspondence in a regulatory binder.
 - d) Consider the potential for needing further committee approvals, including but not limited to:
 - i) HHRI Conflict of Interest Committee
 - ii) HCMC Radiation Safety Committee
 - iii) HHRI Institutional Biosafety Committee