OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Research Team Responsibilities
	SOP #	2.1
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	August 27, 2018

OBJECTIVE
Describe the general responsibilities of the research team in conducting clinical research trails. 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 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
HHRI Non-Payroll Business Expense Guidelines
HHRI Sponsored Project Administration: Guidance and Procedures
HHRI Clinical Research Job Descriptions
HHRI Conflict of Interest Policy

REFERENCES TO RELATED SOPs
All SOPs are applicable to this SOP

ATTACHMENTS
None

1) The Office for Humans Subjects Research (OHSR) and Human Subject Research Committee (HSRC) has jurisdiction over all human subject research as defined by DHHS and FDA definitions.
   a) One or more of the following criteria must be met along with #b:
      i) Performed on the combined campus of HCMC and HHRI
      ii) Performed by any employee of HCMC or HHRI
      iii) Sponsored by HCMC or HHRI
      iv) Involving patient data or patient access obtained through HCMC

   b) The institution is engaged in the research. If there is a question regarding engagement of the institution, involvement of the HHRI Office of Grants and Contracts or other appropriate individuals based on the research proposal should be solicited.

2) The OHSR will provide a determination about whether an activity is research involving human subjects. OHSR staff will review all protocols submitted to the OHSR to determine jurisdiction.
   a) Jurisdiction of the OHSR over the protocol is based on the following:
      i) It meets the definition of human subjects research as defined under the federal regulations.
         (1) For DHHS regulated activity, research involving human subjects is determined by first deciding whether the activity is research as defined by DHHS regulations, and if so, confirming that it involves human subjects as defined by DHHS regulations (45 CFR 46).
         (2) For FDA regulated activity, research involving human subjects is determined by first deciding whether the activity is a clinical investigation as defined by FDA regulations,

and if so, confirming that it involves human subjects as defined by FDA regulations (21 CFR 50).
(3) For studies utilizing a central IRB, please contact HHRI Grants and Contracts by emailing researchinquiry@hhrinstitute.org.

b) There may be activities that might not need to be overseen by the OHSR. These may include quality improvement, program evaluation, surveillance activities, and case reports.
c) Researchers must contact the OHSR with questions about, and guidance for, OHSR jurisdiction on all research or potential non-research activities. Researchers can contact the IRB Coordinator at 612-873-6881.
d) The Chair (or designee) will evaluate on a case-by-case basis and will make a determination regarding jurisdiction.
   i) Quality improvement, program evaluation, and/or surveillance activities are not considered research if the intention of the activity is to improve or inform within the institution. If the results will be generalized outside of the institution, the activity will be evaluated on a case-by-case basis.
      (1) Quality improvement activities are projects that are completed to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. and are usually done for internal purposes only.
      (2) Program evaluation activities are projects with a systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development.
      (3) Surveillance activities are projects that collect, analyze, and interpret health-related data essential to planning, implementing and evaluating health care practice.
   ii) Case reports that are prepared and disseminated for educational purposes are not considered systematic investigations and therefore, not research.
      (1) A case report is a retrospective analysis of a clinical case.
   iii) If the proposed research involves only de-identified data and/or human biological specimens, it may be considered research that does not involve human subjects.
      (1) Research activities involving de-identified data and/or human biological specimens are projects that involve data and/or human biological specimens where all direct personal identifiers are permanently removed from the data or specimens, no code or key exists to link the materials to the original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s).
   iv) If the proposed research involves non-living individuals, it would not fall under OHSR jurisdiction.
      (1) Research activities involving non-living individuals are projects that collect information on deceased subjects.
e) Researchers will be contacted by the OHSR for a final determination of status.
f) If the activity does not fall under the jurisdiction of the OHSR, the researcher shall be referred to Information Security & Privacy, if applicable by the OHSR.

3) Human Subjects Research must be conducted in accordance with:
   a) The ethical principles outlined in the Belmont Report to protect the rights and welfare of research participants (see Appendix C).
   b) All federal, state, local, and other applicable regulations.
   c) Institutional policies and procedures of the HHRI and HCMC.
   d) The OHSR approved protocol.
   e) The safety and welfare of study subjects must be protected by all personnel by being knowledgeable about pertinent regulations, protocol(s), and investigational articles. Suspected or

actual research misconduct may be reported to the HSRC, Institutional Official, OEQCR Director, or the Office of Grants and Contracts.

f) All research team members must comply with federal, sponsor, and HHRI regulations governing disclosure of conflicts of interest.

4) The Principal Investigator (PI) must maintain knowledge of, and overall responsibility for, the conduct of the research. He or she is responsible to:
   a) Personally conduct or supervise the research.
      i) Evaluate proposed study protocols for completeness, budget adequacy, and feasibility for successfully carrying out the protocol.
      ii) Participate in the hiring and training of research team members.
      iii) Ensure that the study team is informed and updated on study related matters with scheduled meetings, memos, emails, or other communication methods pertinent to the research environment.
   b) Ensure that resources are adequate to carry out the research safely. These include, but are not limited to, sufficient time, qualified research team members, equipment, and space.
   c) Delegate study responsibilities to the appropriate research personnel while maintaining overall responsibility.
      i) The PI must assure that all research staff is qualified, including, but not limited to, the appropriate training, education, expertise, credentials, and privileges to perform assigned responsibilities.
   d) Develop and/or review study budgets and maintain fiscal authority for the project. Provide a budget to the assigned HHRI Grant Administrator for review and assistance as needed.
      i) Submit all contracts, material transfer agreements, and confidentiality agreements to the Office of Grants and Contracts for review.
      ii) Document an approval train for charges made to the project.
      iii) Certify effort in accordance with HHRI policy.
   e) Conduct the research according to Good Clinical Practices and other federal, state, local, and other applicable regulations.
      i) Complete and sign the FDA 1572 or Investigator's Agreement (if pertinent).
      ii) Maintain current Minnesota licensure to practice medicine in accordance with license.
         (1) Responsible for all study related medical decisions.
         (2) Dispense study drug, biologic, or device. Maintain records to account for all articles.
         (3) Be familiar with the investigational product, assume responsibility for the investigational product at the trial site, and confirm that the investigational product is used only for enrolled eligible individuals.
      iii) Obtain informed consent.
      iv) Ensure that research is conducted according to the OHSR approved protocol.
      v) Ensure that specific sponsor requirements are fulfilled.
      vi) Participate in monitoring visits and audits (internals, sponsor, regulatory).
      vii) Assure protocol compliance.
   f) Comply with all OHSR and HSRC initial protocol submission and continuing review reporting.
      i) Submit protocol changes, adverse events, and protocol deviations according to policy.
      ii) Respond to all surveillance requests.
   g) Maintain appropriate data and records.
      i) Ensure the validity and confidentiality of the data reported to the sponsor, HSRC, and regulatory authorities.
      ii) Maintain records and study files for the regulated period after study discontinuation or completion.
   h) Complete appropriate federal, sponsor, and institutional financial disclosure forms.

5) Research team members
   a) Manage delegated areas of the research under the direction of the PI. May include, but not be limited to, screening, recruitment, obtaining informed consent, enrollment, follow-up, case report form completion, investigational product dispensing and log maintenance, reporting of adverse events, participating in monitoring visits, audits.
   b) Maintain accurate documentation including, but not limited to, regulatory documents, informed consent forms, HSRC approvals and communications, CRFs, source documentation, investigational drug/device dispensing logs, study-related communication.
   c) Ensure organizational management of all aspects of the investigational trial within delegation of authority.
   d) Communicate all protocol-related issues/problems to appropriate staff.
   e) Maintain correspondence with sponsors, HSRC, and subjects as required by sponsor, federal, state, and local regulations.
   f) Fulfill job responsibilities specific to job title and description.
   g) Complete appropriate federal, sponsor, and institutional financial disclosure forms.
   h) Maintain current Minnesota licensure as appropriate to education.