OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Administrative
	SUBJECT	Resources and Outreach
	SOP #	1.2
	EFFECTIVE DATE	November 2, 2009
	REVISION DATE	January 29, 2020

OBJECTIVE
Describe the processes for maintaining adequate resources for support of the HRPP and provision of outreach to subjects, prospective subjects and the public. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin Healthcare System.

APPLICABLE REGULATIONS AND GUIDELINES
None

REFERENCES TO RELATED SOPs
SOP 1.3

ATTACHMENTS
None

1) Resources in support of the HRPP
   a) The Hennepin Healthcare Research Institute (HHRI) will follow and refine procedures to assess and readjust resources for the support of the HRPP.
   b) Administrative Management Committee meetings will be conducted monthly to discuss operational and budgetary issues, needs, or changes, and short- and long-term future goals. Attendees include senior representatives of the following offices:
      i) HHRI Operations
      ii) HHRI Communications
      iii) HHRI Finance and Accounting
      iv) HHRI Grants Administration
      v) HHRI Human Resources
      vi) HHRI Information Systems
      vii) HHRI Office for Education & Quality in Clinical Research (OEQCR)
      viii) HHRI Purchasing
      ix) HHRI Veterinary Services
      x) Office for Human Subjects Research
   c) Future short-term (one year duration) and long-term operational and budgetary planning will begin in the third quarter of each year. Planning will be based on needs, requests, and feedback identified by members of the Administrative Management Committee and HHRI staff. Items that will be addressed include, but are not limited to:
      i) Space
      ii) Personnel

iii) HRPP education programs
iv) Legal counsel
v) Conflict of interest
vi) Quality improvement planning
vii) Community outreach
viii) IRB resource planning

2) Outreach
   a) The OEQCR contact information will be publicly available on the HHRI website for current, prospective, or past research participants to discuss problems, concerns, or questions; obtain information; or offer input with an individual who was unaffiliated with the specific research protocol.
   b) Items that may be discussed include, but are not limited to:
      i) Explanations concerning the research process
      ii) Providing information about clinical research done at HHRI
      iii) How and where to find studies based on the caller's needs
      iv) Discuss problems, concerns, or questions
      v) As appropriate to the content of the call, callers may be referred to the Office for Human Subjects Research, Principal Investigator, or applicable research personnel.
   c) De-identified information that is provided to the public is kept in the OEQCR database including the nature of the question and answers/direction given to the caller. Uncharacteristic or worrisome findings will be shared immediately with the Institutional Official, the Vice Chair of the Office for Human Subjects Research, or the Principal Investigator as appropriate.
   d) Data collected will include, but not be limited to:
      i) Number of individuals looking for research participation opportunities and type of opportunities requested (i.e., phase I, hypertension)
      ii) Number of individuals looking for information concerning clinical research
      iii) Individuals looking for volunteer opportunities within HHRI
      iv) Complaints received from research participants
      v) Resolution to all inquiries
   e) The OEQCR will revise the "Becoming a Research Volunteer" brochure as needed. The OEQCR will collaborate with the HHRI Corporate Communications Manager to ensure the latest edition is available on the HHRI website, and is available to distribute to outpatient clinics, clinical areas, and persons interested in research. The OEQCR will also distribute copies to interested parties as requested.
   f) OEQCR staff will conduct internal or external training or presentations as requested regarding the research process or the rights of a research participant.
   g) The OEQCR will collaborate with the HHRI Webmaster and Communications Manager in evaluating and updating applicable information and pages on the HHRI website.
   h) The HHRI Communications Manager will update the HHRI website with varying articles, posts, and videos to allow prospective participants and the community to observe various aspects about the research process. HHRI researcher publications,

based on HHRI sponsored research projects, are posted annually on the HHRI website.

i) Website analytics will be collected yearly for the following web pages and/or links:
   i) About Hennepin Healthcare Research Institute
   ii) Our Research with a focus on the main institutional focus areas
   iii) Newsroom
   iv) About Medical Research
   v) Volunteer for a Study
   vi) Becoming a Research Volunteer Brochure
j) Outreach analytics will be collected at the time of the annual assessment of the Human Research Protection Program (SOP 1.3).