Handling Concerns and Suggestions Regarding Human Research and the HRPP

OVERVIEW
The Human Research Protection Program (HRPP) office is responsible for review and inquiry of all concerns or suggestions regarding human subjects research conducted at SJH entities. Concerns or suggestions may be presented to the HRPP by participants, their family members, investigators, research staff, or any person with concerns. Issues regarding Human Subjects Research or HRPP will be resolved as fairly and amicably as possible through a cooperative exchange of information.

PROBLEMS, CONCERNS, OR QUESTIONS ABOUT HUMAN SUBJECTS RESEARCH
The goal of the HRPP is to provide a safe, confidential, and reliable channel for participants and/or their representatives to present problems, concerns or questions. Participants can contact the HRPP office via mail, email, telephone, or anonymously via the webpage feedback tool.

Principal Investigator Responsibilities
Investigators must promptly submit reports of problems or concerns that involve potential risk to the rights, safety, or welfare of participants or others to the HRPP for review.

Problems or concerns that do not involve risk to the rights, safety, or welfare of participants or others should be submitted at the time of Continuing Review.

When subjects have questions about their rights as research participants, researchers should direct questions to the HRPP Office.

HRPP and IRB Responsibilities
Problems, concerns, and questions are handled confidentially. When complainants request to remain anonymous, HRPP staff and the IRB will do what is permissible to meet this request as permitted under the law.

Upon receipt of a problem or concern, HRPP staff will initiate the following process:
- Obtain complainant contact information;
- Obtain a detailed description of the problem or concern;
- Obtain a proposed resolution of the problem or concern from the complainant, if applicable;
- Ensure sufficient information is available by conducting inquiries for additional information, when necessary;
- Confirm with the Institutional Official for St. Joseph Health whether the reported problem or concern as a major or minor issue;
- Work with the appropriate parties to develop and carry out a resolution; and
- Follow up with the complainant.

If the report is an Allegation of Noncompliance, the report will be handled according to SJH guidance on Noncompliance in Human Subjects Research.

Major problems or concerns that involve a potential risk to the rights, safety, or welfare of participants or others may be forwarded to the IRB for review. The following are a list of possible determinations by the IRB; however, additional actions may be warranted as applicable:
• The event constitutes an unanticipated problem and/or serious or continuing noncompliance
• Acknowledge and accept the investigator’s corrective action plan
• Require modifications to the informed consent
• Require modifications to the protocol when permissible
• Increase monitoring of subjects
• Increase frequency of continuing review
• Observation or monitoring of the research
• Educational intervention
• Suspension of all or parts of the research
• Termination of the research
• Refer to the appropriate institutional entity
• Request additional information from appropriate parties for further IRB review

Minor concerns that do not involve potential risk to the rights, safety, or welfare of participants or others will be considered and handled on a case by case basis.

Upon final determination of the reported problem or concern, the HRPP Office and/or IRB will provide a response in writing, and/or a follow up phone call to the complainant (and other applicable parties) within a reasonable timeframe, but no later than 10 business days of the determination of the HRPP and/or IRB.

When the IRB determines that an unanticipated problem or serious or continuing noncompliance has occurred, or when the IRB suspends or terminates approval of research, a report will be processed according to the SJH guidance for Mandated IRB Reporting to Institutional Officials and External Agencies.

SUGGESTIONS TO IMPROVE THE HRPP PROCESSES
Investigators and other research staff are encouraged to resolve difficulties in real time by direct communication between the investigator and HRPP staff. In addition to real time discussions via email and telephone, the HRPP holds quarterly teleconference meetings with researchers that can be used as a forum to present suggestions or discuss any opportunities to improve. When practicable, any difficulties and suggestions will be addressed by a consensus to improve standard operating procedures of the HRPP.

Please email suggestions to HRPP@stjoe.org.