1 PURPOSE

1.1 This guidance establishes the procedure for enhancing understanding of human research with participants, potential participants, and their communities and conducting outreach activities for increased involvement to human research participants and their communities.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

3.1 To comply with the ethical principal of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities.

3.2 The Center for Research (CFR) ensures the availability of information and resources to improve community awareness and involvement with research at Sharp HealthCare (SHC).

4 RESPONSIBILITIES

4.1 The Director of Research is responsible for ensuring the respect for human participants and their awareness of and involvement in SHC research protocols.

4.2 Investigators, site clinical research coordinators, and designees are responsible for day–to-day assurance of compliance with all aspects of the HRPP, including participant awareness and outreach activities.

4.3 Investigators, site clinical research coordinators, and designees involved in human research protocols are responsible for maintaining respectful interactions with participants, involving research participants at every stage, enhancing appropriate safeguards, answering questions in a complete and sensitive manner, and participating in outreach and educational activities for participants and their communities.

5 PROCEDURES:

5.1 Informed consent forms associated with research activities are to be reviewed and approved by the SHC Institutional Review Board (IRB) to ensure that procedures are in place to facilitate the ability of research participants to ask questions, express concerns, or voice complaints to the CFR, IRB, or investigator.

5.2 SHC enhances the understanding of human research with participants, potential participants, and communities, as appropriate, using a variety of methods. These include, among others:

- 5.2.1 Regular ad hoc printed and online communications.
- 5.2.2 General and specialized research communications available at Sharp.com/research.
- 5.2.3 Internal resources for investigators, site clinical research coordinators, and their designees to share with the research community on SharpNet under “Institutional Review Board.”
- 5.2.4 Individual and group meetings and presentations.
- 5.2.5 Hosted events, such as workshops, seminars, and training courses.

5.3 To involve and inform current and future research participants, in accordance with the Belmont Report principle of Respect for Persons, the CFR maintains a “Research Participants” page on the Sharp.com/Research website. This page provides resources for current and future research participants, including:

- 5.3.1 The opportunity to submit concerns, review trial information, and receive feedback.
- 5.3.2 Participant Brochure. See *BROCHURE: Should I Take Part in Research? (HRP-104)*.
- 5.3.3 Oncology Research Participant Brochure. See *BROCHURE: Oncology Research (HRP-125)*
- 5.3.4 Sharp Mesa Vista Research Participant Brochure. See *BROCHURE: Sharp Mesa Vista Clinical Research Center (HRP-126).*
- 5.3.5 Links to government websites where research information may be obtained (e.g., OHRP, FDA, NIH).

5.4 For SHC investigator-initiated research, investigators solicit and incorporate community input as appropriate in the design (including reducing invasiveness), implementation, and dissemination

of research. Based on the type of research, investigators may employ one or more of the following methods, among others: (*WORKSHEET: Community Involvement [HRP-341]*).

- 5.4.1 Planned community sessions
- 5.4.2 Community advisory groups
- 5.4.3 Participant advocates
- 5.4.4 Partnerships with community-based organizations
- 5.4.5 Community-based participant research design methodologies

5.5 Investigators, site clinical research coordinators (CRCs), or their designees distribute information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants, their designated representatives, and the community to discuss concerns, raise questions, obtain information, and provide input on the design of future studies.

- 5.5.1 This information is disseminated by investigators to all persons who are going to participate in the human research protocol. In addition, this information is posted on Sharp.com/Research website.
- 5.5.2 Contact information for reporting complaints or concerns is provided in the informed consent, participant brochure, and the Sharp.com/Research website.
- 5.5.3 Research participants are invited via the Sharp.com/Research website to contact the CFR or IRB staff to provide feedback and/or obtain information about human subjects' research and SHC HRPP activities.

5.6 All communications will be acknowledged and forwarded to the appropriate individual within the organization for handling and follow-up. While the CFR and IRB expect a prompt resolution, the time frame is dependent on the complexity of the complaint or concern.

5.7 Feedback from investigators and other research community members regarding the consent process, formal and informal evaluations, and audits are used as input to develop SHC's HRPP improvements, including community awareness and outreach activities. See *FORM: Education Continuous Quality Improvement (CQI) Assessment (HRP-232)*.

5.8 The Center for Research periodically evaluates its community involvement activities and makes changes, when appropriate, to improve outreach methods; adjust content and materials; and collaborate and educate others on updating such activities.

- 5.8.1 The Community Involvement Task Force, led by the Director of Research, will monitor and evaluate the HRPP's community outreach activities. The Task Force uses *WORKSHEET: Outreach Activity Evaluation (HRP-350)* to track and evaluate the usefulness of each specific HRPP outreach activity
- 5.8.2 The Director of Research or designee also evaluates and reports community outreach activities using *TEMPLATE: Human Research Protection Program – Quality Improvement Report (HRP-565)*
  - 5.8.2.1 Provide a copy of the report to the institutional official or designee.
  - 5.8.2.2 Work with the institutional official to make program modifications as needed.

6 MATERIALS

- 6.1.1 BROCHURE: Should I Take Part in Research? (HRP-104)
- 6.1.2 BROCHURE: Oncology Research (HRP-125)
- 6.1.3 BROCHURE: Sharp Mesa Vista Clinical Research Center (HRP-126)
- 6.1.4 FORM: Education Continuous Quality Improvement (CQI) Assessment (HRP-232)
- 6.1.5 WORKSHEET: Community Involvement (HRP-341)
- 6.1.6 WORKSHEET: Outreach Activity Evaluation (HRP-350)
- 6.1.7 TEMPLATE: Human Research Protection Program – Quality Improvement Report (HRP-565)

7 REFERENCES

7.1 www.sharp.com/research

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.