	<b>SOP: Outreach and Community Involvement</b>		
	NUMBER	DATE Last Reviewed	PAGE
	HRP-004	5/1/2022	Page 1 of 1

**1. PURPOSE**

- 1.1. This SOP 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.
- 1.2. This procedure begins when a human subjects' research study is initiated at Texas A&M University.
- 1.3. This procedure ends when the outcome of the human subjects' research is disseminated.

**2. REVISIONS FROM PREVIOUS VERSION**

- 2.1. None.

**3. SOP STATEMENT**


- 3.1. The Human Research Protections Program (HRPP) makes information and resources available to improve community awareness and involvement with research at TAMU 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.

**4. RESPONSIBILITIES**

- 4.1. The Institutional Official is responsible for ensuring the respect for human participants involved in TAMU research protocols and promoting participant awareness and outreach activities.
- 4.2. Site investigators are responsible for day-to-day assurance of compliance with all aspects of the Human Research Protection Program (HRPP), including participant awareness and outreach activities.
- 4.3. Investigators 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 TAMU 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 HRPP, IRB, or investigator.
- 5.2. TAMU 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 communications.
  - 5.2.2. General and specialized research communications available on the institutional website.
  - 5.2.3. Internal resources for investigators to share with the research community on the HRPP website.
  - 5.2.4. Individual or group meetings as requested.
- 5.3. To involve and inform current and future research participants, in accordance with the Belmont principle of Respect for Persons, HRPP maintains a "Participant Information" page on the TAMU HRPP website. This page provides resources for current and future research participants, including:
  - 5.3.1. The opportunity to submit concerns, questions or comments, and receive feedback.
  - 5.3.2. Participant Information. See *INFORMATION SHEET (HRP-004): Becoming a Research Volunteer*.
  - 5.3.3. Links to government websites where research information may be obtained (e.g., OHRP, FDA, NIH).
- 5.4. For TAMU investigator-initiated research, investigators incorporate community input as appropriate in the design, implementation, and dissemination of research. Based on the type of research, investigators may employ one or more of the following methods, among others:
  - 5.4.1. Planned community sessions
  - 5.4.2. Community advisory groups
  - 5.4.3. Participant advocates

	<b>SOP: Outreach and Community Involvement</b>		
	NUMBER	DATE Last Reviewed	PAGE
	HRP-004	5/1/2022	Page 2 of 1

5.4.4. Partnerships with community-based organizations

5.5. Investigators make available information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives or their community to discuss concerns, raise questions, obtain information, complaint about the research, or ask questions about rights as a research participant, or provided input on the design of future studies.

5.5.1. This information is available to all persons who are going to participate in the human research protocol.

5.5.2. Contact information for reporting complaints or concerns is provided in the informed consent and the TAMU HRPP website.

5.5.3. Research participants are invited via the TAMU HRPP website to contact the HRPP or IRB staff to provide feedback and/or obtain information about human subjects' research.

5.6. Any form of participant communication received by the HRPP or investigator will be acknowledged and forwarded to the appropriate individual within the organization for handling and follow-up. While a prompt resolution is expected, the time-frame is dependent on the complexity of the complaint or concern.

5.7. Feedback from investigators and other research community members, the consent process, formal and informal evaluations, reviews and audits are used as input for improvements to the TAMU HRPP program plan, including community awareness and outreach activities.

5.8. The HRPP 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. These evaluations take place in an informal, ongoing manner. HRPP staff will report both positive and negative feedback regarding community awareness and outreach activities to the HRPP Director or designee, who tracks the input and recommends changes to improve community involvement.

5.8.2. The HRPP Director or designee summarizes the feedback annually to formally evaluate its outreach activities and determine:

5.8.2.1. The specific community outreach activities being used; and

5.8.2.2. Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these.

**6. MATERIALS**

6.1.1. INFORMATION SHEET (HRP-004): *Becoming a Research Volunteer*

**7. REFERENCES**

7.1. AAHRPP I.4.B, I.4.C