

Effective Date: 3/15/20	Original Issue Date: 7/1/11	Revision No.: 01	SOP No.: 135	Page 1 of 2
Hartford HealthCare Human Research Protection Program Participant Outreach Activities				

**1.0 Purpose:**

- 1.1 Hartford HealthCare (HHC) is committed to ensuring that educational opportunities are offered to research participants, prospective research participants, and community members which will enhance their understanding of research involving human participants at HHC
- 1.2 The purpose of this policy, therefore, is to delineate the types of outreach activities offered by the HHC Human Research Protection Program (HHC HRPP) and describe the procedures for documentation and evaluation of those activities.

**2.0 Definitions:**

- 2.1 N/A

**3.0 Procedure:**

- 3.1 Types of information available and activities offered:
  - 3.1.1 The “Information for Research Participants” page on the “Research” website will be maintained and updated as needed. The website provides several resources to increase public awareness and educate potential research participants.
    - 3.1.1.1 Content includes links to the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), the OHRP pamphlet regarding research participation (“Becoming a Research Volunteer: It’s Your Decision”), the NIH pamphlet on HIPAA and Research (“Letting Your Personal Health Information Be Used and Shared for Research”), and access to The Belmont Report and the federal regulations.
    - 3.1.1.2 The IRB/HRPP website also encourages subjects, families, or others with any questions or concerns regarding participation in research to contact the HRPP Director directly and includes appropriate contact information.
  - 3.1.2 HRPP staff will offer to give presentations about participation in research to various patient support groups to foster an understanding of the research process in general. Other topics that may be included in presentations include a brief history lesson on the protection of human subjects, what to expect from the informed consent discussion, HIPAA, etc. Content will be tailored to meet the needs of the particular group.
  - 3.1.3 Investigators and study teams are encouraged to report to the HRPP Office any educational outreach activities offered and conducted by their clinical/research area that promotes understanding of participation in research for the purposes of tracking and evaluation.
    - 3.1.3.1 In addition, many research areas conduct “Satisfaction Surveys”. Investigators are encouraged to report any feedback (positive or negative) to the HRPP Office that may have bearing on improvement of our outreach activities.

Effective Date: 3/15/20	Original Issue Date: 7/1/11	Revision No.: 01	SOP No.: 135	Page 2 of 2
Hartford HealthCare Human Research Protection Program Participant Outreach Activities				

- 3.2 The HRPP Director will perform a formal annual assessment of the adequacy of outreach activities.
- 3.2.1 During the formal evaluation the HRPP Director will consider the specific community outreach activities being utilized and take into consideration any formal evaluative components that are part of the activity (for example, attendee evaluations that are completed and handed in to the presenter after a presentation).
- 3.2.2 This component of the assessment will include:
- 3.2.2.1 The scope, content, and adequacy of outreach activities and resources.
- 3.2.2.2 Whether the research community is using the website resources described above;
- 3.2.2.3 Whether the research community is using other educational materials to inform prospective participants about their rights and welfare as research participants.
- 3.2.2.4 Whether additional resources are needed to improve participant outreach activities
- 3.2.3 The HHC HRPP also periodically evaluates its outreach activities and makes changes when appropriate. In addition to the formal annual evaluation described above, informal, ongoing feedback is encouraged. All IRB and HRPP staff, members and Chairs/Vice-Chairs of the IRB, and research study teams should report both positive and negative feedback about all HRPP outreach activities to the HRPP Director. He/she will then be responsible for ensuring that the input is documented and changes or improvements are implemented. He/she will include a summary of any ongoing material changes in the annual evaluation report.
- 3.3 The results of these assessments will be used to establish both the adequacy of current outreach activities and any additional resources that may be needed to meet the needs of the research community regarding participant outreach.

**4.0 Documentation:**

4.1 N/A

**5.0 References:**

5.1 N/A

**6.0 Revision History:**

Rev #	Initials	Effective Date	Description of Change(s)
00	CLB	7/1/11	New Issue
01	CLB	3/15/20	General review

Element 1.4.B