



Human Research Protection Program / Institutional Review Board
Standard Operating Procedure
2018 Common Rule

**For Studies Initially Approved on
or After January 21, 2019**

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1 Participant Outreach

MaineHealth is committed to ensuring that educational opportunities are offered to research participants, prospective research participants, and community members, which will enhance their understanding of human subjects research at MaineHealth and provide them the opportunity to provide input, seek information, and express concerns.

The following procedures describe how MaineHealth fulfills that responsibility.

1.1 Outreach Resources and Educational Materials

1. The ORC dedicates a section of the website to research participants entitled “For Participants.” This website includes resources, such as Frequently Asked Questions (FAQs), brochures, and a listing of relevant research participation-related links.
2. The website includes information regarding how to contact MaineHealth with any questions or concerns about specific research projects or research in general.
3. The website includes a “Contact Us” link that allows members of the community to ask questions, express concerns, or provide feedback. Provision of contact information by the person is optional.
4. MaineHealth periodically provides presentations related to research to community organizations.
5. The MaineHealth Research Institute (MaineHealthRI) periodically holds “Open Houses” to which members of the public are invited

1.2 Evaluation

On an annual basis, MaineHealth evaluates its outreach activities and makes changes when appropriate. In order to formally evaluate its outreach activities, the ORC Director will review:

1. The specific community outreach activities being used
2. Whether or not these community outreach activities have an evaluative component (e.g., evaluation instrument distributed to participants), and if so whether the feedback was positive, negative, or neutral and if any suggestions were made that could be used to enhance future activities.
3. The number of times the participants’ website is visited
4. Feedback provided via the “Contact Us” mechanism on the “Participant Outreach Corner”
5. Feedback provided from other sources (unaffiliated IRB members, investigators, research staff, students, etc.)

The results of the review 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.