

but the requirements for proper training and the ethical conduct of research in human studies research are the same. Any issues involving non-compliance of non-exempt human studies research will be dealt with in a similar fashion as described above regarding notification of funding entities.

18. Participant Outreach

It is essential that research participants and potential research participants have pertinent information about any research in which they are eligible and wish or agree to take part and that they have information about their rights as a research participant. The Leadership Team will assist in the further development and evaluation of the effectiveness of HRPP participant outreach activities and assess best practices to insure the protection of and information for participants.

18.1. Consent form Requirements

In accordance with regulations at 45 CFR § 46.116 (a)(6-7) and 21 CFR § 50.25 (a)(6-7), each consent form is required to contain:

- Contact information of the Investigator (or his/her staff) for any questions, concerns or problems the participant may have about the research.
- Where to go and whom to contact (and contact information) in the event of a research-related injury when medical interventions or treatments are involved in the research.
- Contact information of the CHS (or other appropriate IRB or ethics committee) for any questions the participant may have about their rights as a participant in research or any complaints or concerns about the research.

18.2. CHS Contact Information and Procedures

The contact for research participants in the CHS office is the ORSP Director (617-432-0651), who handles all calls in a confidential manner. The ORSP Director may take down the caller's name and contact information, or if the caller does not wish to provide that information the call will be treated in the same respectful and serious manner as with an identified caller. The ORSP Director will take notes on the call and will follow-up with the Investigator, especially regarding any complaints or to confirm understanding of the research project (or parts of it, as pertinent to the question of the participant) as it was approved by the CHS.

Depending on the nature of the call, the ORSP Director may advise the participant to call the Investigator or his/her research personnel directly, or may act as the liaison between the two parties. If a serious allegation is made against the Investigator or his/her research personnel, the ORSP Director will treat the allegation in the same manner as noted regarding non-compliance investigations noted in Section 14 of these policies.

18.3. HMS and CHS Websites

Information for research participants, such as participants' rights and whom to contact with any pertinent questions, is available on the CHS website in English and in Spanish. Additionally, participants may submit research questions or comments online. Additionally the HMS website offers a link entitled "Consumer Information" which also links to a consumer health information site. This site will also contain links to the ORSP website noted above and links to information for search participants at the OHRP website. The HMS Consumer Information website also include link to the Longwood Seminar series encompassing various aspects of research.