

PARTNERS HUMAN RESEARCH COMMITTEE  
GUIDANCE DOCUMENT AND INFORMATION SHEET

**Questions, Concerns, or Complaints from Subjects or Family Members**

The Brigham and Women's Hospital (BWH), the Faulkner Hospital (FH), the Massachusetts General Hospital (MGH) and Partners HealthCare are committed to protecting the rights, safety and welfare of subjects participating in research conducted by BWH, FH or MGH. Consistent with this commitment, the Partners Research Consent Form template includes a section that addresses whom to contact if subjects or family members have questions, concerns or complaints about the research. This section includes the name of the investigator responsible for the research and his/her contact information as well as the name and contact information for others on the study team who are available to answer the subject's questions or address any concerns or complaints they might have about the research or their participation in the research. The Partners Research Consent Form template also includes the telephone number for the Partners Human Research Committee should subjects wish to discuss their rights as a research subject, their concerns about the research, or a complaint about the research with someone not directly involved in the research. When the PHRC waives the requirement for the investigator to obtain a signed consent form, contact information for the investigator is included in a study information sheet or other written statement about the research, or in other written materials used during the recruitment and consent process. PHRC contact information is available to subjects, family members, and the public on the PHRC website.

Subjects are encouraged to ask questions or voice any concerns or complaints they may have about the research or their participation in the research during the consent process and throughout the study period. The investigator is responsible for answering all questions, addressing all concerns, and responding to all complaints raised by subjects to the best of his/her ability.

Subjects are also encouraged to contact the Partners Human Research Committee office if they have any concerns that they do not want to discuss with the research staff, e.g., feeling pressured to take part in the research or, after enrollment, to continue to take part.

**Handling Questions, Concerns, or Complaints**

Prospective subjects and subjects enrolled in the research may ask questions or voice concerns or complaints directly to the investigator responsible for the research, a member of the study staff, or to a representative of the Partners Human Research Committee, verbally or in writing before, during or after taking part in the research.

Complaints Received by Investigators/Study Staff

Investigators are responsible for ensuring that subject complaints are handled in a respectful manner and that subjects are not penalized or lose any benefits they are receiving or have a right to receive. Complaints should be resolved thoroughly and in a timely manner.

When, despite his/her best efforts, the investigator is unable to resolve a complaint thoroughly or in a timely manner, the complaint should be referred to the Director of Human Research Review and Compliance. The Director will work with the investigator and Director and Chair of the Partners Human Research Committee and other hospital representatives, such as the Privacy Officer or Accounting and Finance, as appropriate, to resolve the complaint. The PHRC will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days.

Investigators must document all complaints received from subjects or family members and their resolution and report them to the PHRC at continuing review.

#### Complaints Received by the Partners Human Research Committee Office

Complaints received by the Partners Human Research Committee office will be addressed by the Director of Human Research Review and Compliance or one of the Assistant Directors. When the complaint is received by telephone, the person receiving the complaint will record the information provided by the complainant. The Director or his/her designee will inform the investigator of the complaint and request a response to the issues raised in the complaint. The PHRC will maintain privacy of the complainant where privacy is a concern.

The Director will work with the investigator and Director and Chair of the Partners Human Research Committee and other hospital representatives, such as the Privacy Office, Accounting, and Research Compliance, as appropriate, to resolve the complaint. Investigators and study staff are expected to cooperate with internal efforts to investigate and resolve complaints. The PHRC and/or the investigator will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days of receipt of the complaint. The Human Research Office will maintain records of subjects' complaints and their resolution, and a copy will be retained in the applicable protocol file.

Investigators must document all complaints received from subjects or family members and their resolution and report them to the PHRC at continuing review.

#### Remedial Action, Suspension or Termination of Research, and Noncompliance

The Director and Chair of the Partners Human Research Committee will be responsible for determining whether remedial action is necessary. Should the complaint result in an allegation of noncompliance or be cause for suspension or termination of the research, the PHRC will follow the procedures outlined in following policies: Noncompliance in Human-Subjects Research; Suspension or Termination of Human-Subjects Research; and Reporting to Institutional Officials and Regulatory Agencies.