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## Division of Academic Affairs

### Human Research Protection Program

#### **FACT SHEET: RESEARCH SUBJECT ADVOCACY**

The functions of Research Subject Advocacy (RSA) at Baystate Health are fulfilled through a variety of elements encompassed in our comprehensive Human Research Protection Program (HRPP). The HRPP provides integration of the multiple individuals, groups, committees, and functions necessary to promote and achieve true advocacy for research subjects through best practices.

1. The HRPP uses a variety of mechanisms to reinforce the rights of individuals to voice their complaints or concerns about any aspect of research or research oversight. HRPP policies provide direction for the investigation and handling of questions, concerns, and complaints from research participants that are properly addressed by investigators, IRB Chairs, the HRPP Director, and the Institutional Official.
  - a. Consent documents include contact information for the IRB in the event the research staff are unavailable, or in the event the research participant wishes to speak with someone other than the research staff, for research participants to obtain answers to questions about the research, to voice concerns or complaints about the research, and to obtain answers to questions about their rights as a research participant.
  - b. The Academic Affairs home page on the internal website and the Baystate Health external website pages for research participants include a “Suggestions or Concerns” submission link.
  - c. An independent corporate compliance hotline (SilentWhistle) is available to all employees.
  - d. Baystate Health provides information about research on its external website. This includes resources for research participants including Frequently Asked Questions (FAQs), Research Contacts at Baystate Health, and relevant research-related links. The website also includes contact information for the HRPP Office so that research participants can communicate complaints, concerns, questions, or provide input on research participation.
  - e. The Research Participant’s Bill of Rights is provided in English and Spanish versions electronically on the Baystate Health external website, the Institutional Review Board’s internal website, and in printed format for distribution and posting.
2. The HRPP demonstrates its commitment to best practices in research through AAHRPP accreditation and by:
  - a. Providing education through a variety of formats including live events, web-based training and resources, and content distributed by newsletters and emails.
  - b. By providing standardized templates for Investigator Standard Operating Procedures.

- c. By requiring professional certifications of eligible clinical research staff (e.g., CCRC and CCRP certification) and promoting certifications of HRPP/IRB staff (e.g., CIP and CIM certification).
  - d. By conducting for-cause and not-for-cause reviews of active research with an educational focus.
  - e. By engaging the services of professional external consultants to provide periodic reviews of and education for the HRPP and all of its components.
3. The HRPP provides for timely suspension of research activities when necessary to protect the rights, safety, and welfare of research participants through policy by designating the authority to suspend when warranted to the Institutional Official, the HRPP Director, the IRB Chairs, and the IRBs themselves. By providing for mechanisms outside of formal IRB action, investigations and actions can be initiated in as rapid a manner as necessary to protect research participants.
  4. HRPP policy development is led by the HRPP Director with active participation by the IRB Chairs, the Research Integrity Officer, and the Institutional Official. Feedback on policies and forms is actively sought from the research community at large and incorporated into the continuing review of policies.
  5. The research community at large is engaged and actively participates in program and policy development through forums, surveys, committee involvement, and email solicitation.