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Review and Processing of Problems, Complaints, Concerns, and Questions from Research Subjects				

## 1.0 Purpose:

- 1.1 To define the process by which problems, complaints, concerns, and questions from research subjects are received, reviewed and processed by the Hartford HealthCare (HHC) Human Research Protection Program's (HRPP) Office. This document also defines the process for addressing questions from subjects about their rights as research participants.

## 2.0 Definitions:

- 2.1 **Subject** – An individual who has signed a consent form to participate in a research study that is both conducted by HHC personnel and also overseen by the HHC IRB. In the case of subjects who are minors or who are otherwise not legally competent to sign a consent form, the “subject” will be considered the parent/guardian or legal representative, as appropriate, who has signed the consent form for the study participant.
- 2.2 **Complaint** – A statement made by a patient (or subject) or patient representative that a patient’s reasonable expectation of care and services is unsatisfactory or unacceptable.
- 2.3 **Grievance** - A written or verbal complaint by a patient (or subject), or the patient’s representative, regarding the patient’s care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the Hospital’s compliance with the Medicare Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights. In addition, a grievance is any claim of discrimination under state or federal law or regulation, including claims alleging discrimination based on race, color, national origin, age, disability, or sex.
- 2.3.1 A written complaint is always considered a grievance.
- 2.3.2 Whenever a patient/representative requests their complaint be handled as a formal complaint or grievance, or requests a response from the hospital, then the complaint is a grievance and the grievance process will apply.

## 3.0 Procedure:

- 3.1 Problems, complaints or concerns may be received in the HRPP office by conventional mail, email, FAX, or telephone.
- 3.1.1 Problems, complaints or concerns received by conventional mail or FAX are stamped with the Institutional Review Board (IRB) will be logged to record the date received and forwarded to the HRPP Director for initial review.
- 3.1.2 Problems, complaints or concerns received by telephone are forwarded to the HRPP Director.
- 3.1.2.1 In the case of telephoned problems, complaints or concerns where the caller is unwilling to be forwarded, the recipient of the

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call will create a written record of the conversation, including contact information for the caller, and forward the written record of the call to the HRPP Director for review.

- 3.1.3 Problems, complaints or concerns received by e-mail are electronically forwarded to the HRPP Director for initial review.
  - 3.1.4 All problems, complaints or concerns, regardless of the manner in which they are received, must be forwarded no later than one business day from receipt in the HRPP Office.
  - 3.1.5 Upon review of the issue, the HRPP Director, in consultation with the IRB Chair, will make a preliminary assessment whether the complaint warrants immediate suspension of the research project and whether the issue rises to the level of a hospital-defined grievance requiring notification of the Patient Advocate Office in the Patient Experience Department.
  - 3.1.6 A response is made promptly to the subject, within 7 business days of receipt of the problem, complaint or concern.
- 3.2 All Issues that are considered in the review of the problem, complaint or concern include:
- 3.2.1.1 Existence of valid consent document in IRB files (as defined by 21 CFR 50.25; 45 CFR 46.116)
  - 3.2.1.2 Proper study documentation in IRB files
  - 3.2.1.3 Past history of study team
  - 3.2.1.4 Validity of subject's complaint
  - 3.2.1.5 Effect on risk/benefit to subject
  - 3.2.1.6 Liability for HHC
  - 3.2.1.7 Whether the complaint or concern involves an allegation or finding of non-compliance in accordance with HRPP Policy # 925 – Handling of Non-compliance.
- 3.3 If the review indicates a need, the HRPP office may request to perform an audit of the research. The review process may include any of the following:
- 3.3.1 Meeting with the complainant
  - 3.3.2 Meeting with the Principal Investigator (PI) and relevant study team members.
  - 3.3.3 Meeting with the HHC Office of Experience.
  - 3.3.4 Meeting with HHC Counsel or other HHC personnel.
  - 3.3.5 If the review indicates that the complaint or concern involves an allegation of non-compliance, HRPP Policy # 925 – “Handling of Non-compliance” will be followed.
- 3.4 **Questions from Research Subjects about their Rights**
- 3.4.1 Questions from research subjects about their rights as research participants will be directed to the HRPP office.

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- 3.4.2 These may also be received in the HRPP Office by conventional mail, e-mail, FAX or telephone.
- 3.4.3 Questions from research subjects about their rights received by conventional mail or FAX will be logged to record the date received and forwarded to the HRPP Director for initial review.
- 3.4.4 Questions received by telephone are forwarded to the HRPP Director.
- 3.4.5 Questions received by e-mail are electronically forwarded to the HRPP Director.
- 3.4.6 The HRPP Director reviews the question about a subject's rights against the IRB's record of the applicable study and either responds directly to the subject or seeks counsel from appropriate personnel before responding.
- 3.4.7 A response is made promptly to the subject, within 7 business days of receipt of the question.
- 3.4.8 The study's PI will be informed of the subject's question unless the subject requests otherwise, or the HRPP Director is advised by appropriate personnel to do otherwise.
- 3.4.9 A separate file on such questions and their follow-up will be maintained in the HRPP office.

**4.0 Documentation:**

- 4.1 Receipt and tracking of subject problems, complaints, concerns, and questions will be documented and tracked using the "IRB Phone Line and E-Mail Subject Inquiry Log".
- 4.2 Issues deemed to constitute non-compliance will be documented and maintained in accordance with HRPP Policy # 925 – "Handling of Non-compliance".

**5.0 References:**

- 5.1 Hartford HealthCare hospital wide Policy (Hartford Hospital, MidState Medical Center, Hospital of Central Connecticut)– "Complaint and Grievance Management" (August 2017)

**6.0 Revision History:**

Rev #	Initials	Effective Date	Description of Change(s)
00	CLG	7/1/11	New Issue
01	CLB	3/15/20	General review. Added definition of complaint, updated process and institutional policy reference

Element I.4.A.

