Office of Clinical Research (OCR) Guidance on Managing Public Inquires and Communication Instructions

Purpose: To provide guidance for the communication of research information with the public. OCR staff refers all inquiries from the news media to the Office of External Affairs (HOP 2.4.6 External Affairs). OCR staff maintains privacy and confidentiality related to information shared (HOP Chapter 11 Privacy Policies apply).

Overview: Type of communication subject to this procedure:

1. Prospective participant looking for a study to enroll in such as:
   a. Specific disease/type of study inquiry
   b. General inquiry (e.g. needing healthy volunteers)
2. Participants currently enrolled seeking information related to:
   a. Current enrollment in a study
   b. Complaints, concerns or questions
3. General inquiries for specific medical treatments
4. Health providers seeking to refer patients
5. Research industry (potential, current and previous research sponsors).
6. Initial communication may come via telephone, in person verbally or by email.

Instructions:

1. OCR staff will handle communication from current or prospective participants in the following manner:
   a. For requests to volunteer as a subject in a study, OCR staff will:
      (1) Ask the caller about the type of research in which he/she has interest.
      (2) Search for the type of research requested through the following sources as needed: the HSC Find a Study Website; the IRB protocol database; and/or the HSC departmental web sites; HSC public information news release site (Office of External Affairs).
(3) Relate study contact information to the caller or give names of departmental research coordinators or nurses identified for referral.

(4) If the caller has a computer available, instruct on the use/navigation to access:

(a) HSC Find a Study Website and Information for Research Participants web page for information to consider before becoming a volunteer and questions to ask.

(b) ClinicalTrials.gov.

b. OCR staff will handle communication from persons with concerns, questions or complaints in the following manner:

(1) Obtain the reason for call (i.e., nature/description of concern or compliant).

(2) For non-research inquires related to need for treatment of an illness, refer to the department that treats that type of illness via the Medical Arts and Research Center (MARC) patient appointment/clinic referral numbers.

(3) If caller has a concern or complaint related to research, assure the caller that the concern or complaint will be investigated and that assignee will initiate follow up communication to resolve the issues presented. The following information should be obtained:

(a) The name of the study

(b) Dates, times and names of involved personnel as applicable

(c) Request call back/contact information:

(d) Complete name, phone number, and address (include email address if available).

This information should be provided to the IRB Director, Chair or designee for review in accordance with the IRB Complaints Policy and Procedure.

c. OCR staff will handle communication from external healthcare providers or industry in the following manner:

(1) Obtain necessary information: nature of call, person’s name and call back information.
(2) Refer to other HSC departments or divisions, Principal Investigators, Office of Institutional Review Board, Clinical Trials Office, Office of Sponsored Programs or to OCR Manager or his/her designee, as applicable.