STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH

Title: Research-Related Patient Education and Recruitment Materials

SOP Number: SP-204

1. PURPOSE:
This Standard Operating Procedure (SOP) describes the process for UH Departments participating in Clinical Research that are interested in creating patient-facing material pertaining to their research area(s). The goal of this SOP is to clarify the difference between general educational materials and study recruitment materials, and to provide guidance for UH Departments.

2. SCOPE:
This SOP provides instruction and sets minimum standards for UH Departments regarding the difference between general educational materials and study recruitment materials. General educational materials do not need to be submitted to the IRB for approval. In comparison, study recruitment materials require approval by the IRB. This material must be submitted with each study that could potentially recruit from it.

3. RESPONSIBLE INDIVIDUALS:
This SOP applies to UH Department staff involved in research and UHCRC staff members who may be involved in this process (e.g., Recruitment, Education / Compliance, IRB).

4. DEFINITIONS:
General Educational Materials - Materials created with the intent to provide general research education to patients, including (1) a definition of research; (2) what to expect when participating in research; (3) potential risks and benefits of participating in research; and/or (4) information about research the Department has conducted in the past. This material does not specifically intend to recruit patients and therefore, does not mention details or criteria of current research studies.

Study Recruitment Materials - Any items that target patients with the intent to enroll them into particular research studies. This type of material requires submission to and approval from the IRB prior to use. Types of materials that fall under this category are: flyers, verbiage, brochures, social media post content, posters etc.

5. POLICY STATEMENT:
This SOP is to help clarify the difference between general educational materials and study recruitment materials, as well as provide recommended content and language for general educational materials.

Approved by the UH CRC Research Policy Oversight Committee
6. PROCEDURES:

6.1 General Education Materials may include:
   6.1.1 A description / definition of the term “research”.
   6.1.2 What someone can generally expect when participating in research.
   6.1.3 General conditions or topics that are typically studied in the department (so long as language makes it clear that it is not a list of currently ongoing trials, or a promise that there will be an available trial on that topic).
   6.1.4 Typical locations where research is conducted (so long as the language makes it clear that it is not a list of currently available locations, or a promise that that specific location will be an available).
   6.1.5 Contact information for study teams or recruitment hotlines if people want to learn more about what trials are available.
   6.1.6 Names and information about researchers in the department.

6.2 General Education Materials may NOT include:
   6.2.1 Specific study titles.
   6.2.2 Specific eligibility information.
   6.2.3 Specific participation benefits (e.g., a no-cost health examination).
   6.2.4 Specific drugs, devices, or interventions to be studied.
   6.2.5 Mention of whether financial compensation/reimbursement might be provided.
   6.2.6 A promise or implication of extra or better treatment if someone participates in research.

6.3 It is not permissible for either general education materials or recruitment materials to:
   6.3.1 Include irrelevant, inappropriate, or misleading pictures or images.
   6.3.2 Mention specific amounts of financial remuneration or overemphasize that remuneration is available.
   6.3.3 Claim (explicitly or implicitly) that a study or intervention is safe or effective.
   6.3.4 Claim (explicitly or implicitly) that a study is equivalent or superior to any other drug, biologic, device or intervention.
   6.3.5 Include terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is “investigational”.
   6.3.6 Use exculpatory language.
   6.3.7 State or imply a certainty of favorable outcome or benefits.

6.4 Please note that both general education materials and recruitment materials should only be distributed in appropriate and approved locations. For example, UH does not permit
posting in elevators or bathrooms. It is also not appropriate to leave pamphlets in a waiting area that is not associated with the department without prior permission.

APPROVALS

Approved by Dr. Grace McComsey, Vice President of Research, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center – January 29, 2020