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1. Overview

Purpose

These guidelines describe the process for identifying and recruiting prospective study participants while fulfilling ethical responsibilities for protecting the rights, safety and welfare of participants.

2. Research Study Advertising and Recruitment

All study advertising, recruitment materials, and recruitment methods must be reviewed and approved by the IRB prior to use for recruitment and must comply with Drexel HRP Requirements. Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters or news stories do not require IRB approval. All ads referencing Drexel University and all publicity for studies must be reviewed by the Drexel University Marketing and Communications Department prior to use. If the study is industry sponsored, the study sponsor should also approve all recruitment materials.

Advertising and recruitment materials are reviewed by the IRB to ensure the material is accurate and not coercive or unduly optimistic. All recruitment materials must **avoid**:

- Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the research plan.
- Claims, either explicitly or implicitly, that the test article (drug, biologic or device) is safe or effective for the purposes under investigation.
- Claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device.
- Using terms like "new treatment," "new medication," or "new drug" without explaining that the test article was investigational.
- Promising "free medical treatment" when the intent was only to say participants will not be charged for taking part in the investigation.
- Emphasis on payment or the amount to be paid, such as bold type or larger font on printed media.
- Offers for a coupon good for a discount on the purchase price of an investigational product once it has been approved for marketing.
- The inclusion of exculpatory language.

3. Advertising & Identification of Individuals for Potential Study Participation

3.1 The study team may utilize various recruitment methods as reviewed and approved by the IRB. Recruitment methods may include:

- The PI reviewing records from his/her own patient population, as applicable
- Contacting other Drexel University Departments, affiliate sites, or clinical partners with potential access to populations meeting the study requirements for collaboration in research recruitment. Please note that appropriate contracts may be required for recruitment at affiliate sites.

- Referrals (avoid family members, no finders fees)
- Use of flyers, social media posts, newspaper/television ads, or recruitment emails to broad or targeted populations
- Third-party applications (e.g., ResearchMatch, BuildClinical, Qualtrics Panels) – Please ensure that a third-party risk assessment has been completed prior to utilization of a third-party system, per Drexel's Third Party Risk Management (TPRM) processes: (https://drexel.edu/it/security/services-processes/risk-management/).

3.2 Advertising should be limited to the information the prospective participants need to determine their eligibility and interest. This includes:

- Name, address and contact of the clinical investigator/coordinator and research facility
- Condition under study and/or the purpose of the research
- Criteria that will be used to determine eligibility for the study (can summarize)
- A brief list of participation benefits, if any (e.g., a no-cost health examination)
- The time or other commitment required of the subjects

3.3 Utilization of websites such as www.clinicaltrials.gov, National Cancer Institute's cancer clinical trial listing and the government-sponsored AIDS Clinical Trials Information Service is acceptable. Other websites may be utilized as long as the information does not promise or imply any certainty of cure of other benefit beyond what is stated in the protocol and Informed Consent Form.

4. Contacting Individuals for Potential Study Participation

The study team must contact prospective participants using an IRB approved communication method entailing information about the research study and whom to contact if the individual is interested. Personal devices, such as texting with personal cell phones, may not be used for research participant recruitment. In addition, ensure any use of a third-party system has approval by Drexel's TPRM.

If applicable, study investigators or designated personnel may reach out directly to their own patient population for research recruitment. Care should be taken to minimize coercion or undue influence if the study investigator is the healthcare provider the prospective participant(s). The PI or study team may also solicit study participants through direct personal contacts in the community.

5. Discussing Study Details with the Prospective Participant

The informed consent process begins with initial contact with the prospective participant, even prior to the prospective participant receiving and signing a copy of the informed consent form. The IRB-approved recruitment and enrollment process must be followed for all recruitment, prescreening, screening, consent, enrollment procedures, and records retention.

A standard recruitment process might include:

- After identifying a potential study participant, a designated member of the study team may complete preliminary screening review or prescreening, if applicable (e.g. basic chart review, interest survey).

- The study team member may reach out to the prospective participant and describe the study details. This can be done in person or remotely via telephone or Zoom meetings.
- If the individual expresses interest in study participation, they may be scheduled for a screening visit and provided with the study consent form for review.

6. Responsibilities

6.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

6.2 Principal Investigator Responsibilities

The Principal Investigator retains overall responsibility for the study conduct, documentation, and oversight. The PI is responsible for overall study recruitment, including contacting prospective participants, contacting other physicians, determining the suitability of the prospective participants, discussion of study details with prospective participants, and obtaining appropriate approval and permission prior to use of recruitment materials (e.g., IRB approval, Drexel University Marketing & Communications approval, department or site-specific marketing approval).

6.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for preparation of and obtaining approval of advertising and recruitment materials, and discussion of study details with the prospective participants. Study personnel may be involved in additional recruitment responsibilities as delegated by the PI.

7. Resources

- 45 CFR 46 – Protection of Human Subjects
- 21 CFR 50 – Protection of Human Research Subjects
- FDA Guidance on Recruiting Study Subjects
- UMAC-2 Drexel University Marketing, Advertising and Promotional Materials
- Drexel University Third Party Risk Management

8. Revision and Workgroup Members

8.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Recruitment of Research Participants

8.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

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