**PURPOSE:** This SOP describes the steps for fulfilling the regulatory and clinical requirements involved in study subject recruitment for clinical research conducted at Kent State University (KSU).

**SCOPE:** This SOP applies to the Investigators and key personnel who conduct human subjects research activities at KSU, the research teams who wish to place IRB approved printed advertisements for recruitment purposes at KSU.

**RESPONSIBILITY:** The PI and his/her key personnel are responsible for proper recruitment of study subjects into research studies approved by the KSU Institutional Review Board (IRB) or a KSU relied upon IRB.

**DEFINITIONS:**

**Advertisement:** Printed material that is intended to be seen or audio material that is intended to be heard by prospective research subjects to solicit and induce their participation in a study. This may include direct advertising such as newspaper, radio, television, bulletin boards, posters, flyers, letters, postcards, email, internet advertisements, and other electronic media. This may also include direct communication one-on-one, in small groups, or in large assembly.

**Electronic Medical Record (EMR):** A computerized medical record created in an organization that delivers care, such as a hospital or physician's office. Also may be referred to as Electronic Health Record (EHR).

**Exclusion Criteria:** A list of criteria, any one of which excludes a potential subject from participation in a research study.

**Inclusion Criteria**: The criteria that potential participants must meet to be eligible for participation in a research study.

**Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. The Informed Consent Form (ICF) may also be referred to as Informed Consent Document (ICD).

**Key Personnel:** Individuals who are directly involved in conducting research with human participants, or are directly involved with handling identifiable private information related to those participants in the course of a research project, regardless of the source of research funding. Students who are directly involved in either aspect of research involving human subjects are considered key personnel.

**Recruitment:** The process that employs inclusion and exclusion criteria and is used by investigators to enroll appropriate participants into a research study.

**PROCEDURE:**

1. The PI and key personnel will develop a recruitment plan that is approved by the Sponsor, if applicable.
2. The study/ regulatory coordinator will provide detailed information regarding study subject recruitment methods and forms must be included in the initial IRB application to determine if recruitment is fair and equitable. Examples of recruitment methods include:

* Clinic patients’ electronic medical records (EMRs)
* Study subject / provider referrals
* Telephone
* Recruitment letter
* Recruitment packet if applicable
* Advertisements
* Posters
* Use of appointment books
* Newspaper, TV and radio advertisements
* Internet postings
* Disease support groups
  1. Include any necessary approval(s) from sites where the advertisements may be placed.

1. The study team will ensure that clinical trials are registered on clinicaltrials.gov as required by federal regulation.
2. The Investigator and study team will assess the effectiveness of the recruitment plan.
   1. Monitor progress and assess results of the recruitment plan.
   2. Keep the PI and sponsor apprised of actual enrollment in relation to recruitment goal.
   3. Create alternative strategies if actual enrollment is less than enrollment goal.

|  |  |
| --- | --- |
| **REFERENCES:** | 21CFR50.20, 50.25  21CFR56.111(a)(3); 56.111(b)  21CFR812.20(b)(11)  Belmont Report, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research April 18, 1979  FDA Information Sheet-Recruiting Study Subjects-Information Sheet Guidance for Institutional Review Boards and Clinical Investigators  ICH 4.1.1.29 |
| **RELATED POLICIES:** | SOP #103: Responsibilities of the Research Team  SOP #201: Regulatory Documentation  SOP #402: Informed Consent Process |
| **APPENDICES:** | Appendix X:Recruitment Materials Cover Sheet: Recruitment and Advertising Materials for Human Subjects in USF Health Clinic Waiting Areas  Appendix Y: Attestation Statement for Recruitment and Advertising Materials for Human Subjects in USF Health Clinic Waiting Areas |
| **REVISION HISTORY:** Keep a running history of all revision dates. | |

|  |  |  |
| --- | --- | --- |
| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |