SUBJECT RECRUITMENT

PURPOSE: This SOP describes the steps for fulfilling the regulatory and clinical requirements involved in study subject recruitment for clinical research conducted at the CRC.

SCOPE: This SOP applies to the Investigators and key personnel who conduct human subjects research activities at the CRC, the research teams who wish to place IRB approved printed advertisements for recruitment purposes in the USF Health clinic waiting areas, and the OCR who will maintain the brochure carousels in the following waiting areas.

- Morsani Center for Advanced Healthcare
- South Tampa Center for Advanced Healthcare
- Byrd Alzheimer's Institute
- Children's Medical Services

RESPONSIBILITY: The PI and his/her key personnel are responsible for proper recruitment of study subjects into research studies approved by the University of South Florida (USF) Institutional Review Board (IRB) or a USF relied upon IRB. The Office of Clinical Research (OCR) will be responsible for the purchase, set up, and maintenance of the brochure carousels within the clinic locations as listed in this SOP.

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).

DEFINITIONS (cont.):

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. Some recruitment methods include:
    - Clinic patients' electronic medical records (EMRs)
    - Study subject / provider referrals
    - Telephone
    - Recruitment letter
    - Recruitment packet if applicable
    - Advertisements-Recruitment Guidelines in USF IRB manual for more information
    - Posters
    - Use of appointment books
    - Newspaper, TV and radio advertisements
    - Internet postings
    - Disease support groups

    2.1. Include any necessary approval(s) from sites where the advertisements may be placed.

3. The study team will ensure that clinical trials are registered on clinicaltrials.gov as required by federal regulation.

4. The Investigator and study team will assess the effectiveness of the recruitment plan.
    4.1. Monitor progress and assess results of the recruitment plan.
    4.2. Keep the PI and sponsor apprised of actual enrollment in relation to recruitment goal.
    4.3. Create alternative strategies if actual enrollment is less than enrollment goal.

PROCEDURE (cont.):

5. Recruitment and Advertising Materials for Human Subjects in USF Health Clinic Waiting Areas:

   5.1. Only current, IRB approved advertising materials will be permitted on displays. The IRB approval must include the method/location where the recruitment material will be used, as applicable. A generic statement in the IRB application such as "recruitment material will be placed in the USF Health clinic waiting areas" is acceptable for this purpose for USF relied upon IRBs that require the location of recruitment material to be specified.

   5.2. The OCR will disseminate information via email to research teams advising them to obtain IRB approval, if necessary, prior to utilizing this recruitment method.

   5.3. Each study coordinator using the displays to advertise their studies will be asked to sign an attestation (Appendix U) that they have read this procedure.

   5.4. A complete recruitment materials submission packet includes
   a. Recruitment Materials Cover Sheet (Appendix T)
   b. Attestation Statement (Appendix U)
   c. Hard copies of IRB approved recruitment material to be placed in the carousels

   5.5. All research staff interested in posting clinical trial(s) materials in the USF Health clinic waiting areas should contact an OCR Research Nurse.

   5.6. Designated OCR staff and each individual research coordinator will arrange to meet at a mutually agreed upon place and time where, the research coordinator will provide OCR staff with a complete recruitment materials submission packet.

   5.7. In lieu of a meeting, the research coordinator may send a complete recruitment materials submission packet via campus mail to OCR, attention Recruitment.

   5.8. OCR staff will contact the research coordinator to request any missing items from the submission packet.

   5.9. Copies of recruitment materials will not be distributed until the OCR is in possession of a complete recruitment materials submission packet

   5.10. OCR staff will scan a copy of the recruitment materials submission packet and store them in the OCR SharePoint.

   5.11. OCR staff will place and manage all recruitment brochures on displays on a regular basis, at a minimum of once per week.

   5.12. The OCR will notify the research coordinator via email or phone if study materials need to be replenished. The coordinator will provide designated OCR staff with additional hard copy recruitment materials. The OCR is responsible for placing the brochures on the displays.

   5.13. The research coordinator is responsible for notifying the IRB and OCR immediately of any changes in recruitment and advertising materials and/or change in study

status (e.g., closed to accrual) so that the recruitment material may be removed or replaced as applicable.

5.14. OCR will conduct periodic quality assurance checks to confirm continuous IRB approval remains in effect for the recruitment material.

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
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