| UC San Diego<br>Senior Associate Vice Chancellor in Health Sciences<br>Office of Clinical Research | SOP Number | OCR:005<br>Page 1 of 3 |
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| | Date: | 04/02/2025 |
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| | Approved by: | Susan Little |
| SOP TITLE: RESEARCH PARTICIPANT RECRUITMENT PROCEDURES | | |

## 1 PURPOSE

1.1 This procedure establishes processes that Principal Investigators (PIs) and study personnel under the PI's supervision must follow when recruiting human research participants and conducting initial eligibility screening to ensure that these activities are conducted in an ethical manner and in compliance with federal regulations, institutional policies, and IRB requirements.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

## 3 REQUIREMENTS

3.1 Recruitment materials include any forms of communication used to inform potential participants (and their providers) about the research, and includes printed and electronic communications such as flyers, advertisements, emails, recruitment and telephone scripts, internet postings, and/or any other communication materials or methods.

3.2 All recruitment materials and methods for identifying participants must be approved by the IRB prior to implementation. Some website recruitment may be permitted, however, if the PI determines that internet recruitment complies with requirements of OIA-094 SOP; Human Research Internet Recruitment.[1] Any modifications to these materials after initial approval must be resubmitted to the IRB for review before implementation.

3.3 Recruitment materials should be appropriate for the study population demographics.

3.4 The Food and Drug Administration (FDA) considers recruitment advertising to be part of the informed consent process,[2] and as such, these activities require IRB approval and should be documented in the study records.

3.5 For some studies,[3] the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. However, (verbal only/written) informed consent must be obtained prior to initiation of any screening tests that are performed solely for the purpose of determining eligibility for research.

3.6 Recruitment and pre-screening activities may not commence until IRB approval is obtained.

## 4 RESPONSIBILITIES

4.1 The PI, as the leader of the research team, is responsible for ensuring that recruitment activities by members of the research team under their supervision comply with these procedures, with the IRB-approved protocol, ethical standards, and applicable regulatory requirements.

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[1] OIA-094 SOP: Human Research Internet Recruitment

[2] FDA Guidance: Recruiting Study Subjects

[3] FDA Guidance: Screening Tests Prior to Study Enrollment

4.2 All research personnel involved in identifying, contacting, and evaluating potential research participants at UC San Diego Health Sciences are responsible for following this procedure.

## 5 PROCEDURE

5.1 The PI or designee must develop a written study recruitment plan for submission to IRB.

5.2 The recruitment plan will detail the following recruitment methods and tools, as applicable.

5.2.1 If identification of potential participants will employ existing data sources, such as medical records, registries, or existing study databases or records, the recruitment plan must include, and the IRB must approve, the process for accessing and reviewing these records, the type(s) of data to be reviewed and/or retained, the plan to protect identifiable information contained in these records, and the plan for the use of the data.

5.2.1.1 To comply with the "minimum necessary" standard of HIPAA regulations, the PI should carefully consider what information is necessary to conduct the study activities and request access for those items.

5.2.2 If identification of potential participants will involve outreach to individuals, the recruitment plan must include, and the IRB must approve:

5.2.2.1 How the potential participants will be identified (e.g., from the investigators' clinic or appointment records, via face-to-face contact at clinical visits, or by any other means).

5.2.2.2 How identifiable data will be used and/or retained.

5.2.2.3 Methods that will be used to contact potential participants.

5.2.2.3.1 If potential participants will be contacted via email, a template email must be submitted to and approved by the IRB.

5.2.2.3.2 If potential participants will be contacted via telephone, a telephone script detailing the recruitment conversation must be submitted to and approved by the IRB.

5.2.2.3.3 The telephone script and/or email will inform potential participants about what data will be collected and how that data will be used and/or retained for the study, whether or not they proceed to enroll in the study.

5.2.3 If identification of potential participants will involve referrals from others, the recruitment plan must include, and the IRB must approve, from whom and how the referrals will be solicited and received, and how the potential participants will be contacted following the referral and if participants must consent before being contacted.

5.2.3.1 If potential participants will be contacted via email, or will contact the study team via email, a template email must be submitted to and approved by the IRB.

5.2.3.2 If potential participants will be contacted via telephone, or will contact the study team via telephone, a telephone script detailing the recruitment conversation must be submitted to and approved by the IRB

5.2.3.3 The telephone script and/or email will inform potential participants about what data will be collected and how that data will be used and/or retained for the study, whether or not they proceed to enroll in the study.

5.3 Submit all recruitment materials to the IRB for review and approval.

5.4 After IRB approval, conduct pre-screening recruitment conversations with study participants.

5.4.1 Using the recruitment telephone script and/or email, as applicable, provide information to the potential participant about the study in alignment with the IRB-approved materials.

5.4.2 Document the recruitment conversations in the study records.

5.4.3 Record the outcome of the pre-screening process on screening logs or participant study records, as required by the study protocol.

5.4.4 Obtain written informed consent from study participants prior to conducting any study-specific clinical procedures.[2]

## 6 MATERIALS

6.1 OCR-102 Sample Screening and Enrollment Log

## 7 REFERENCES


7.1 FDA Guidance: Recruiting Study Subjects

7.2 FDA Guidance: Screening Tests Prior to Study Enrollment

7.3 HHS: Minimum Necessary Requirement