1. PURPOSE

1.1 This procedure establishes the criteria that must be met before investigators may receive and use participant information from the UC San Diego Clinical Research Volunteer Registry maintained by the Altman Clinical and Translational Research Institute (ACTRI).

1.2 This procedure does not apply to any other registries or participant databases.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 GUIDANCE

3.1 UCSD has developed a Web page at clinicaltrials.ucsd.edu that captures clinical trial data from ClinicalTrials.gov into a UCSD-specific Web site, enabling participants who are interested in clinical trials at UCSD to search only those trials. The Web page enables interested participants to contact the ClinicalTrials.gov contact at UCSD directly and/or to enter their data into a Clinical Research Volunteer Registry for possible matching with current or future recruiting studies.

3.2 The Clinical Research Volunteer Registry seeks to match participants with available clinical trials through a voluntary questionnaire that can be used for gross eligibility assessment. The Clinical Research Volunteer Registry manager may review the participant's responses and identify a potentially compatible trial or trials, then provide the UCSD study contact with the participant's registry data and contact information regardless of whether this recruitment method has been addressed in the study IRB application and recruitment plan.

3.3 Investigators are not required to submit specific recruitment plans to receive participant information from the Clinical Research Volunteer Registry.

4 RESPONSIBILITIES

4.1 Investigators are responsible for ensuring compliance with this standard operating procedure.

4.2 Investigators who wish to use or receive data from any other registries or participant databases must submit for and receive prospective IRB approval of a suitable recruitment plan before soliciting for or receiving information from those registries or databases.

5 PROCEDURE

5.1 The Clinical Research Volunteer Registry manager must ensure that the following requirements are met prior to providing the UCSD investigator or study contact with the registry participant's data and contact information:

5.1.1 The participant affirmed their agreement to participate in the Clinical Research Volunteer Registry.

5.1.2 The participant data suggests potential eligibility for the study based on the criteria on clinicaltrials.ucsd.edu as derived from ClinicalTrials.gov

5.2 The Clinical Research Volunteer Registry manager will transmit the potential participant's data and contact information to the UCSD investigator or study contact using a secure method (e.g., Monday.com, institutional email using "SECURE:" in the subject line, or similar method).

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

7 REFERENCES

7.1 University of California Policy BFB-IS-3: Electronic Information Security