 INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-094 SOP: Human Research Internet Recruitment				
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1. PURPOSE

- 1.1 This procedure establishes the criteria that must be met before investigators can post information about human subjects research on the internet for recruitment purposes without obtaining prior IRB approval of that internet recruitment information.
- 1.2 This procedure does not apply to internet recruitment where the content is not managed by the investigator or research team (e.g., sponsor websites).

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDANCE

- 3.1 UCSD adheres to Food and Drug Administration (FDA) guidance entitled "[Recruiting Study Subjects](#)"¹ in which the FDA states the following: IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).
 - 3.1.1 The office of IRB administration (OIA) has determined that it is appropriate to extend the FDA's guidance to studies which are not FDA regulated as OIA concurs with the FDA's reasoning in the guidance that IRB review of such postings would not meaningfully add to human subjects research protection. See *OIA-315 WORKSHEET: Advertisements* for additional research advertisement regulatory criteria.
- 3.2 Investigators are not required to submit internet posting(s) to the IRB for approval when the study is approved by the IRB and the criteria outlined in this standard operating procedure are met.

4 RESPONSIBILITIES


- 4.1 Investigators are responsible for ensuring compliance with this standard operating procedure.
- 4.2 Investigators wishing to use internet postings which deviate from the criteria described in Section 5 below must submit for and receive prospective IRB approval before posting.

5 PROCEDURE

- 5.1 Investigators must ensure that the following requirements are met prior to posting recruitment material on the Internet without prior IRB approval:
 - 5.1.1 The only links on the posting are links to:
 - 5.1.1.1 An IRB-approved consent document;
 - 5.1.1.2 An IRB-approved protocol;²
 - 5.1.1.3 An IRB-approved subject facing document or webpage;
 - 5.1.1.4 A link for potential participants to use to provide contact information if the individual is interested in participating;
 - 5.1.1.5 An IRB-approved social media webpage;
 - 5.1.1.6 The study's clinicaltrials.gov listing;
 - 5.1.1.7 Peer reviewed educational material about the condition under study;
 - 5.1.1.8 Support groups for those with the condition under study;
 - 5.1.2 The posting does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document;
 - 5.1.3 Compensation cannot be included as a benefit of study participation;
 - 5.1.4 The posting does not describe risks beyond what is in the consent document;

¹ [FDA Information Sheet: Recruiting Study Subjects](#)

² Such documents may not be able to be made publicly available due to confidentiality provisions. Research teams should check with Sponsors/[Office of Contract and Grant Administration/Office of Clinical Trials Administration](#) prior to making such documentation publicly available.

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- 5.1.5 The posting does not make claims, either explicitly or implicitly, that the investigational intervention is safe or effective;
 - 5.1.6 The posting does not use the term “new” to reference an investigational study intervention, such as “new treatment,” “new medication,” or “new drug,” without explaining that the intervention offered is investigational;
 - 5.1.7 The posting does not include any exculpatory language whereby the sponsor or investigator appears to waive subjects’ rights to payment for research-related injuries;
 - 5.1.8 The description of the study contains brief descriptions of some or all of the following using language pulled from an IRB-approved consent document:
 - 5.1.8.1 Study title
 - 5.1.8.2 Purpose of the study
 - 5.1.8.3 Condition being studied
 - 5.1.8.4 Investigational intervention
 - 5.1.8.5 Basic eligibility criteria
 - 5.1.8.6 Amount of time the participant will be in the study
 - 5.1.8.7 Number of study visits
 - 5.1.8.8 Study procedures
 - 5.1.8.9 Compensation offered to study subjects
 - 5.1.8.9.1 Information about compensation must be in the same font, color, and type size as the rest of the posting and may not be emphasized by bolding, underlining, italicizing, or other means.
 - 5.1.8.10 Study site location(s)
 - 5.1.8.11 How to contact the study site for more information.
 - 5.2 Prior to publication of the posting, the individual submitting the information must attest via written documentation (e.g. a note to file, email, etc.) in the study file³ the following:
 - 5.2.1 The information on the posting complies with this standard operating procedure, and
 - 5.2.2 The principal investigator has read and approved the publication.
 - 5.3 If the posting collects personally identifiable information (PII) from potential participants, the webpage must be compliant with UCSD information technology (IT) policies, including [BFB-IS-3: Electronic Information Security](#).
- 6 MATERIALS**
- 6.1 *OIA-001 SOP: Definitions*
 - 6.2 *OIA-315 WORKSHEET: Advertisements*
- 7 REFERENCES**
- 7.1 [FDA Information Sheet: Recruiting Study Subjects - Guidance for Institutional Review Boards and Clinical Investigators](#)
 - 7.2 [University of California Policy BFB-IS-3: Electronic Information Security](#)

³ The “study file” (also sometimes known as a “site study master file” or “regulatory binder”) is the documentation maintained by the principal investigator/research team. This does not refer to the IRB’s electronic submission system (e.g. Kualii).