

SOP: Clinical Trials Recruitment Websites				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-092	04/30/2017	C. Gates	C. Kiel	1 of 2

1. PURPOSE

- 1.1 This procedure establishes the criteria that must be met before investigators can post information about clinical trials on websites for recruitment purposes without obtaining prior IRB approval of that website recruitment information.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 UC Davis adheres to FDA guidance entitled, Recruiting Study Subjects, 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)

- 3.2 Investigators are not required to submit website posting to the IRB for approval when the trial is approved by the IRB and the criteria outlined in this SOP are met.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Investigators must ensure that the following requirements are met prior to posting recruitment material on a website without prior IRB approval:
- 5.1.1 The webpage does not include photographs;
 - 5.1.2 The only links on the webpage are links to:
 - 5.1.2.1 The consent document;
 - 5.1.2.2 The protocol;
 - 5.1.2.3 An IRB approved subject facing document or webpage;
 - 5.1.2.4 A link for potential participants to use to provide contact information if the individual is interested in participating;
 - 5.1.2.5 An IRB approved social media webpage;
 - 5.1.3 The webpage does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol;
 - 5.1.4 The webpage does not make claims, either explicitly or implicitly that the investigational treatment is safe or effective;

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- 5.1.5 The webpage does not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the treatment offered is investigational;
- 5.1.6 The webpage does not include any exculpatory language whereby the sponsor or investigator appears to waive subjects’ rights to payment for research related injuries;
- 5.1.7 The webpage does not describe risks and benefits;
- 5.1.8 The description of the study is limited to brief descriptions of the following:
 - 5.1.8.1 The purpose of the study;
 - 5.1.8.2 The condition being studied;
 - 5.1.8.3 The investigational treatment;
 - 5.1.8.4 Eligibility criteria;
 - 5.1.8.5 The amount of time the participant will be in the study;
 - 5.1.8.6 The number of study visits;
 - 5.1.8.7 Study procedures
 - 5.1.8.8 Compensation offered to study subjects
- 6 Prior to publication of the webpage, the individual submitting the information must attest to the following:
 - 6.1 The information on the webpage complies with this standard operating procedure; and
 - 6.2 The principal investigator has read and approved the publication.
- 7 If the webpage collects personally identifiable information from potential participants, the webpage must be compliant with [21 CFR Part 11](#) or the [HIPAA Security Rule](#).
- 8 MATERIALS**
 - 8.1 WORKSHEET: Advertisements (HRP 315)
- 9 REFERENCES**
 - 9.1 21 CFR § 50.24
 - 9.2 21 CFR Part 11
 - 9.3 45 CFR 45 CFR Part 160 and Subparts A and C of Part 164
 - 9.4 45 CFR § 46.116
 - 9.5 FDA Guidance Recruiting Study Subjects - Information Sheet