



## **SOP 601: SCREENING, RECRUITING, AND ADVERTISING FOR PARTICIPANT ENROLLMENT**

### **POLICY**

The University of Utah IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the subject or the subject's legally authorized representative if either of the following conditions are met:

- a) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; **or**
- b) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Investigators must abide by the HIPAA Privacy Rule, when applicable (see SOP 802: Privacy and Confidentiality).

The IRB will evaluate recruitment processes (including advertisements) to ensure an equitable selection of participants. Additionally, the IRB considers advertising or soliciting for study participants to be the start of the informed consent process. Therefore, the IRB reviews proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent.

Advertisements should be included as part of the initial study application.

The Investigator must obtain IRB approval prior to the use of all television, radio, print advertisements, e-mail solicitations, letters, websites, and other recruitment methods and materials intended for the recruitment of prospective research participants.

When advertisements are to be taped for broadcast, the IRB must review the final audio or video advertisement prior to approval. The IRB may review and approve the script of an advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final recorded message prepared from the IRB approved script may be conducted via expedited procedures.

The IRB reviews "direct advertising for research participants" which is defined as advertising that is intended to be seen or heard by prospective participants to solicit their participation in a study. This includes any sponsor-provided advertisements or Investigator-drafted advertisements.

Advertisements must be submitted to the IRB in their final form in order to receive IRB final approval for use.

The IRB adheres to the advertising guidelines posted on the IRB website (see Investigator Guidance Series: Recruitment Methods and Investigator Guidance Series: Advertisements).

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



**PROCEDURES**

1. Investigators must describe the plan for screening, recruiting (including any advertising materials), or determining eligibility in the new study application.
2. Investigators must include any advertising materials in the new study application. Any advertising materials developed after IRB approval must be submitted via amendment application.
3. Changes in currently approved procedures for screening, recruiting (including any advertising materials), or determining eligibility must be submitted in the form of an amendment to the IRB for approval prior to implementation.
4. The IRB Chair or designee may review changes to approved procedures for screening, recruiting, or determining eligibility via expedited review (see SOP 402: Expedited Review). Changes to advertising materials (when changes are easily compared to the consent document) may also be reviewed via expedited review. However, the Chair or designee may refer the amendment application to the convened IRB if the IRB reviewer has doubts or other complicated issues are involved.

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