

**Policy Number: 28**

**Title: Research Involving Use of the Internet**

**Date of Last Revision: 01/21/2007**

**Policy:**

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review the use of the internet for human research activities, including participant recruitment, in human subjects research conducted under its jurisdiction.

- I. **IRB Considerations in Review and Approval of Research Activities Involving the Use of the Internet**
  - A. The IRB must review all research activities involving the use of the internet with the same considerations and standards for approval of research (45 CFR 46.111), for informed consent, and voluntary participation as all other research activities under the jurisdiction of the UCI IRB.
  - B. The informed consent process and documentation of such must include all relevant elements of informed consent as listed in the Federal regulations.
  - C. The IRB review must include a consideration for the delineation of personal boundaries (i.e., would the participant consider the access private or public space of the internet).
  - D. The IRB review must consider the risks to the participants and must assure that there is an appropriate level of protection.
    1. The IRB must consider that each communication carries the risk of a breach of confidentiality. Even when data is collected without names, web sites or email programs may still be capable of collecting identifiers.
    2. The IRB must consider that admonishing participants that they must be 18 years of age to participate, does not guarantee compliance.
    3. The IRB must consider all additional requirements for the approval of research that involves a vulnerable population as all other studies recruiting those populations.
  - E. The use of online surveys must include mechanisms, if applicable, for withdrawal such as how to retrieve and discard responses from a participant who has decided to withdraw.
  - F. Because there is no standard for identifying distressed participants online, the IRB must take into consideration potential participant experiences (the sensitive nature of the research) that may be distressing when evaluating the risk/benefit ratio.
- II. **Requirements for Evaluating the Use of the Internet for Participant Recruitment**
  - A. The IRB must approve all materials used for posting recruitment materials on the internet, (e.g. through a website, a banner advertisement, or an email solicitation) (See IRB Policy 22)
  - B. Investigators requesting to recruit through intra-campus email at UCI and UCI Medical Center (UCIMC) must follow the appropriate procedures required by UCI Communications in addition to IRB approval.
  - C. *UCIMC Clinical Trials web page* - If this method is used in recruitment of potential participants, the IRB Application must include this information as a method of recruitment or must be submitted as a modification request for the already approved protocol and provide a completed "UCI Medical Center Clinical Trials Web Page - Standard Research Recruitment Advertisement Form" for IRB approval.

III. **Requirements for Consideration of Data Collection and Security to Ensure Confidentiality of Data**

- A. All data must be protected as it moves along the communication pathways (e.g., from the participant to the server, from the server to the Investigator). Additionally, all databases storing identifiable information or data must be protected regardless of the source creating the data (e.g., encryption of the database, de-identifying the data).
- B. The IRB must review and approve the method and procedures for data collection and security.
- C. Investigators must provide information regarding the transmission and storage of the data.

**References:**

IRB Policy 22, "Advertisement and Recruitment"