Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: X.I
Section: Conduct of Research
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Research Involving the Use of the Internet

Policy:
It is the policy of the Human Research Protections Program (HRPP) 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 HRPP.
   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 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.

C. 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 review and approve all materials used for posting recruitment materials on the internet, e.g. through a website, a banner advertisement, or an email solicitation (See HRPP Policy X.G).
   B. Investigators requesting to recruit through the mass email system at Vanderbilt University Medical Center (VUMC) must follow the appropriate procedures for review and approval by VUMC Communications in addition to IRB approval (See HRPP Policy X.G).
   C. Vanderbilt has a variety of list services and publications such as the Clinical Trials Center’s website. 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 an amendment to the already approved proposal.
III. Requirements for Consideration of Data Collection and Security.
   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.
   D. When an Investigator chooses to have a separate server for data collection or storage, the IRB must review and approve its administration.

References:
The University of Miami’s Collaborative IRB Training Initiative (CITI) online tutorial module 11: “Internet Research”
HRPP Policy X.G