Subject: Procedure for Research Involving the Use of the Internet

Procedure:
This procedure provides guidance for the review of the Human Research Protections Program (HRPP) of the use of the internet for human research activities, including participant recruitment, in human subjects research conducted under its jurisdiction.

I. Investigator Responsibilities.
   A. Should the Investigator wish to use the internet for research activities, he or she will submit the IRB application for review and approval with additional information regarding the specific information and activities to be accessed via the internet.
   B. The Investigator must address the method for obtaining and documenting, when appropriate, informed consent from each participant and provide a mechanism for assuring that participants are of the legal age to consent.
      1. The consent method and materials in final form must be included in the application for review and approval.
      2. When requesting a waiver of consent or a waiver of documentation of consent, the Investigator must submit the supporting information for consideration of a waiver.
      3. When anyone who has access to the internet is a potential participant, it may be difficult to assure comprehension of the consent information. To assure comprehension the Investigator may want to:
         (a) Incorporate short questionnaires into the consent process to assess the potential participant’s understanding of the informed consent content.
         (b) Asking participants to contact the Investigator to discuss the information presented before beginning the study, if applicable.
      4. When sensitive information is gathered via the internet, the Investigator must provide a mechanism for identifying serious distress and providing assistance to participants who may become distressed by the nature of the questions asked.
   C. Copies of the materials, in final form, to be posted on the internet must be submitted for IRB review and approval.
   D. Mechanisms for participants to withdraw. This should include options for retrieving and discarding responses or allowing “no response” as an option for survey questions.
   E. The Investigator should include a description of the security measures in place regarding data collection and storage. The Investigator must keep in mind that even if the data will be collected without names, websites and email programs are capable of collecting identifiers.
      1. When appropriate, the data collection should be transmitted in an encrypted format.
      2. Encryption is also required when a server will be used for data storage.
         (a) The server must be stored in a secure location with limited access only to the Investigator and key study personnel.
         (b) The administration of the server must be maintained by a professionally trained person with expertise in computer and internet security.
         (c) Back-ups of the data should be made, as deemed appropriate, and stored in a secure location.
A plan for destruction of the data must be included in the IRB application or amendment for review and approval.

F. Should the Investigator wish to use the internet for posting of recruitment materials, all documents must be submitted in final form to the IRB for review and approval, prior to its use (See HRPP Policy X.G).

II. IRB Committee Responsibilities.
A. The IRB Chair, a designated Committee Member, or the convened IRB Committee will review the use of the internet for research. Consideration will be given for potential risks to participants and to assure that proper protections are in place to address issues of confidentiality and privacy.
B. Sensitive data must be protected as it moves along communication pathways. The IRB must consider that all communication carries the risk of a breach of confidentiality.
C. The IRB will review all materials in final form to be posted on the internet and used for recruitment of participants in accordance with HRPP Policy X.G.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will pre-review and request any necessary revisions of submitted documents for the use of the internet as outlined for new study submissions.
B. Once the pre-review revisions are received from the Investigator, the RCA will route the study for review following expeditied procedures, or when applicable, place the new study on the next available IRB Committee agenda, assign reviewers, and assure appropriate materials are available. Reviewers are electronically notified once assigned.
C. The RCA will assist reviewers in obtaining additional information that may be requested regarding the use of the internet for research activities.
D. The RCA will notify the Investigator in writing of the IRB Committee’s determinations. This letter requires a signature of the Chair or designated Committee Member.
E. The RCA will process all requests for amendments, serious and unexpected adverse events or unanticipated problems to participants or others, and continuing reviews per corresponding HRPP policies and procedures.
F. Appropriate IRB database entries are to be completed.