



## Guidelines for Using the Internet to Conduct Research Activities

### Policy

This document is designed to assist investigators in addressing the appropriate ethical and practical considerations necessary for protecting human subjects when the Internet is used for research related activities. The Internet has become an increasingly popular and convenient tool for conducting research; however, it has also raised important questions regarding associated risks. This guidance document focuses on the unique issues related to collection of data over the Internet, particularly through the use of online surveys.

#### How is the Internet used for research related activities?

The main categories of Internet use for research are 1) recruitment, 2) observation of Internet activities, and 3) collection of data.

#### Where can I get information about using the Internet for recruitment purposes?

Researchers planning to use the Internet as a tool for recruitment should follow the established IRB guidelines on this topic, which can be found at:

[http://www.childrenshospital.org/~media/Research%20and%20Innovation/Office%20of%20Clinical%20Investigation/cipp\\_081\\_012\\_recruitment.ashx](http://www.childrenshospital.org/~media/Research%20and%20Innovation/Office%20of%20Clinical%20Investigation/cipp_081_012_recruitment.ashx)

#### What do I need to consider if I want to observe Internet activities/chat rooms as part of my research protocol?

While there is presently no specific guidance from the Institutional Review Board (IRB) on research utilizing the observation of Internet activities, or participation in chat room activities, investigators are encouraged to contact the IRB office to discuss any issues and concerns related to such research procedures early in the protocol submission process.

#### Can all surveys performed as part of research utilize the Internet?

No. It is important to note that not all types of research involving surveys are good candidates for online data collection. For example, a questionnaire that may provoke anxiety or emotional distress may not be suitable for the Internet environment. It is important to consider that when research is conducted entirely through the Internet, it is not possible for researchers to assess a subject's reaction to the research, as is possible in more traditional face-to-face or even telephone survey design. The IRB will review protocols that use the Internet on a case-by-case basis to determine whether the procedures outlined are appropriate for the nature of the research.

Likewise, if the inadvertent disclosure of research information could cause significant harm or embarrassment to subjects, the use of the Internet to conduct the research may not be appropriate. The primary source of risk in Internet research is the inappropriate breach of confidentiality, as it is impossible to guarantee the security of data transmitted over the Internet.

### **Do I need to be concerned about whether the subject population has access to computers/Internet and the ability to use computers/Internet?**

Yes, it is necessary to consider that discrepancies in access to computers and the Internet exist, and that some individuals will be excluded from Internet-based research that otherwise may have been able to participate. Investigators must address the bias introduced by conducting research over the Internet in their protocols.

### **What criteria will the IRB use when evaluating surveys performed over the Internet?**

When conducting survey research on the Internet, researchers must adhere to the same basic ethical principles as required in any type of research. However, the use of the Internet for collection of data introduces additional concerns that must be taken into consideration by the investigator in designing a protocol and by the IRB in its review of a protocol. The IRB will use the same criteria normally used to review research protocols, as Internet-based research must offer the same level of protections to human research subjects as research that is conducted through more traditional methods. Additionally, the IRB will review the research to be sure that the additional risks specifically related to Internet activities are minimized.

## **Data Collection and Transmission**

### **What do I need to consider about the authentication of a subject before data collection?**

Researchers need to keep in mind that there is no way to be sure that a respondent to an Internet survey is over 18 or the person the investigator seeks to involve. This is important both scientifically and for the protection of human subjects. It will be important for researchers to have a way to authenticate the identity of the subject responding to a survey. When designing protocols, researchers should consider different methods of authentication. The IRB will consider whether authentication of subjects is appropriately outlined in a research protocol. If data resulting from a project is not valid, any potential risk to subjects may not be justified.

### **Are there any special issues I need to consider regarding the voluntary nature of answering individual questions on an Internet survey?**

Yes. When traditional paper surveys are used, the IRB requires that subjects are given the option of skipping any question that they do not wish to answer. This option is also a

requirement for surveys conducted over the Internet. When researchers design Internet-based surveys, they should include the option for subjects to skip a question and move on to the next one. Completion of any individual question cannot be forced through the use of Internet technology. A screen should also be included at the conclusion of the survey that gives subjects the option of either submitting or recalling their responses.

## **What do I need to consider regarding the electronic transmission of data? Do I need to have data encrypted?**

Yes, security during the transmission of data from the participant's computer to the Web server should be ensured by using a server that employs encryption technology. Encryption should also be utilized when the Web server is a different machine than the one on which the data will be analyzed. Researchers need to specify in their protocols the steps that will be taken to ensure the security of data stored and transmitted using the Internet. For clarification of acceptable methods of encryption, please refer to the following Boston Children's Hospital Information Security manual policies:

*Email use*

*Mobile Device and Laptop Security*

*Safeguarding Electronic Data*

## **Are there special considerations if I want to notify a subject about a study via email?**

Yes, the following considerations need to be taken into account when email is used to transmit data or to provide potential subjects with information about a research study.

- Investigators should be aware that email is not a secure communication mechanism. Furthermore, a subject's email account may be shared with another individual, such as a spouse or family member, or may be monitored by an employer. For these reasons, researchers should not include any sensitive information or the title of a study in emails, if the title itself can reveal sensitive information. Investigators also have a responsibility to inform subjects that some email accounts may be less secure than others. Subjects can take this information into account when choosing which email address to provide to a researcher.
- Investigators should consider the use of Secure Mail. Information regarding this may be found at <http://web2.tch.harvard.edu/ehelp/Documents/securemail.pdf>
- An email may be mistakenly sent to a wrong address. Researchers should take steps to be certain that the email address is correct to be sure emails are received by the appropriate person.
- Precautions should be taken to ensure that subjects will not inadvertently respond to an email that is sent to a study listserv. The blind carbon copy function should be used so subjects cannot view the names of other participants and to ensure that a participant does not respond to all recipients of an email.
- Email should not be used to collect data; instead, investigators can send an email including a link to a secure site, where data can be collected.
- All emails should include instructions such as, "If you have received this email in error, please contact XYZ at Boston Children's Hospital Boston."

## **Data Storage and Disposal**

### **Are there special requirements for data storage?**

- Laptops and computers containing files with research data should be password protected, and individual files should be password protected as well. This is good practice for any research utilizing electronic files.
- Personally identifiable data should be stored separately from research data.
- Extra precautions must be taken when private health/identifiable information is collected. PHI must be stored on an ISD server or an ISD-approved server. Data that is collected as part of a research protocol which includes any of the HIPAA identifiers may not be placed on any personal use device, including home computers, Palm Pilots, PDAs, etc.

### **Are there special requirements for data storage?**

Yes, investigators need to include in their protocol a description of how long the data will be kept and whether it will ever be destroyed. It is important to recognize that copies of electronic data/files are often kept for back-up and security purposes and therefore it may not be possible to state that data will be destroyed.

For general hospital policy about data retention, please refer to the [\*\*BCH Code of Conduct/Compliance Manual Document Retention and Destruction Policy\*\*](#).

## **Informed Consent via the Internet:**

### **Can I obtain informed consent via the Internet?**

For some protocols, the IRB will allow consent to be obtained via the Internet. The investigator must provide rationale as to why it is not practicable to obtain the subjects' written signature on a consent form. In accordance with the regulations pertaining to informed consent, the researcher will need to request a waiver of written informed consent, or to request that consent is obtained through a method other than written consent. Researchers must also consider authentication of the age of subjects if individuals less than 18 will be asked to complete a survey via the Internet.

### **Are there specific ways the IRB would recommend I consider obtaining consent for an Internet survey?**

If obtaining consent through a method other than a written consent form, one option for obtaining informed consent over the Internet is to have the first page of a survey consist of an information sheet/consent form. Then subjects can be required to check a box indicating their consent before beginning the survey. If a waiver of written consent is not granted, researchers may consider having subjects download a consent form and sign a printed copy to mail to the researcher. After receipt of the consent form, the researcher would provide the subject with a PIN to access the survey.

## **Are there special additional requirements for what needs to be included in the consent for surveys conducted on the Internet?**

Yes. In addition to the standard information that must be included in all consent forms, investigators need to include the following information in consent forms/information sheets for online research.

- A statement that information transmitted over the Internet can never be completely anonymous and that confidentiality in Internet research can never be completely guaranteed.
- The steps that will be taken to ensure the security of data stored and transmitted over the Internet
- Information associated with the subject that will be attached to a survey (IP address, email address, etc.)
- Contact information for the investigator, so the potential subject can ask questions

## **Commercial Web Survey Vendors vs. Internal:**

### **Can I use a commercial web survey vendor?**

The IRB does not ban the use of commercial survey vendors, but it is required that vendors meet a minimum standard to ensure that CH research subjects are given adequate protection. Investigators are responsible for acquiring all of the information listed below and for including it as part of the protocol application. Once the information is reviewed and found to be acceptable we hope to publish a list of acceptable vendors so that other investigators will be made aware of them and do not need to repeat collection of the same information.

1. What security measures are in place to protect data during transmission from the browser to the Web server, and during transmission to the researcher's computer? Does the organization use SSL technology?
2. What security measures are in place to protect data stored on the Web server?
3. What does the organization do with the information it gathers about site visitors?
4. How long are log files kept?
5. Is data received date and time stamped?
6. What are the organization's data storage and back-up policies and processes?
7. What are the organizations privacy and confidentiality policies?
8. Who in the organization has access to the data being gathered and stored?
9. What happens to the copy of the data file the organization has (from the back-up) when the research project is finished?
10. Who in the organization is available if other questions arise?

## **Are there internal Boston Children's Hospital services, software and servers that can be utilized for electronic surveys?**

Yes, The Clinical Research Center (CRC) offers Children's researchers access to Web-based software to quickly develop, deploy, and manage interactive surveys through the Internet. Researchers should contact the CRC directly for more information about this service.

## Related Content

## Document Attributes

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