

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
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Title: <b>Conducting research on the Internet</b>	Date Effective 5/20/04	Supercedes P&P dated

## BACKGROUND

The Internet offers unique opportunities for researchers who wish to study social and behavioral interactions in a virtual environment and presents new challenges to researchers and the IRB.

## JHSPH POLICY AND PROCEDURES

Although federal regulations do not specifically address issues to consider when conducting research on the Internet, investigators and CHR should consider the basic review criteria when designing or assessing this type of research:

1. risks are minimized and are in relation to anticipated benefits;
2. selection of subjects is equitable;
3. informed consent will be obtained from all prospective subjects and will be appropriately documented;
4. when appropriate, there is a safety monitoring board;
5. there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data; and
6. additional safeguards are included to protect vulnerable populations.

Researchers should specifically address the following points when submitting a CHR application for Internet research to the committee. (*See the CHR Application guidelines for additional requirements.*) The ethical principles of respect, beneficence and justice apply to research conducted on the Internet just as they do to more traditional approaches.

### Recruitment Process

It is usually inappropriate to recruit subjects directly from discussion groups, chat rooms, etc., as this may be an invasion of privacy. Acceptable recruitment methods include posting notices on bulletin boards or asking site coordinators to distribute announcements to their list members.

All research involving human subjects should include a broad range of populations to ensure that all persons share in the benefits and bear the burdens of research. Consideration must be given in the research design to attracting populations that are diverse with regard to race, gender and economic status to avoid issues of non-representative sampling.

If the research will not involve children, a plan must be developed for screening out minors. Monitoring software and adult check systems, although not foolproof, may be used. If the research will involve children, the additional protections for research involving children provided in

the Federal regulations apply (assent, parental permission, etc.). (See the CHR Guidance on Inclusion of Children in Research.)

*Points to address in the CHR Application:*

1. *Describe the process for recruitment:*

- *Will you have access to a mailing list that will be sent to individuals' email addresses? If Yes, what is the source of the mailing list?*
- *Will an announcement be posted by a site administrator? If Yes, provide evidence of approval from the site administrator.*

2. *Explain how potential subjects will respond to the advertisement.*

- *Will potential subjects respond via email, post office mail or be directed to a website?*

Note that ALL advertisements, including Internet-based ads, must be reviewed and approved by the Committee.

### Risks and Benefits

Two major sources of harm in conducting research on the Internet arise from the lack of direct contact with subjects and the potential for breaches of confidentiality. Indirect contact with subjects may not allow researchers the opportunity to deal with a subject's reaction to a certain situation, or, because of the fluid nature of virtual communities, follow-up may not be possible.

Conducting research on the Internet is not likely to cause physical injury, but it may increase the risk that a subject's identity will be exposed. The identity of subjects and personal information about them may unknowingly be disclosed during data gathering, data processing or data storage. Clearly defined technical information, easily understood by a broad range of persons, must be in place when interacting with subjects. To the extent possible, additional protections should be developed to protect against inadvertent disclosure of identity.

Internet research also raises concerns that misleading information may weaken the validity of the data collected. Problems created by pseudonyms, multiple submissions and overt deception deserve special consideration.

*Points to Address in the CHR Application:*

1. *How will you ensure that responses from a population not intended to be included in the sample are screened out?*
2. *How will multiple submissions be detected and screened out?*
3. *How will accuracy of the data be ensured?*

### Consent

Researchers must address how informed consent will be obtained and authenticated. Generally, the written consent of all subjects who participate in research must be obtained unless a waiver or alteration has been granted by the Committee. (A waiver for obtaining parental permission is granted in limited circumstances.) Written documentation of consent may include using a

procedure in which the subject must click a consent page that includes all of the elements of informed consent before accessing the survey. Another option is for the subject to print a consent documentation page that is then signed and sent by mail to the researcher. The researcher, upon receipt of a signed consent document grants the subject access to the survey.

*Points to Address in the CHR Application:*

1. *What is the process for obtaining consent?*
  - *Is a waiver of informed consent being requested?*
  - *Is a waiver of written informed consent being requested?*
  - *If children will be involved in the research, how will parental permission be obtained?*
2. *What is the process for ensuring the subject's understanding of the research?*
3. *What is the process for answering any questions the subject may have about the research?*
4. *Describe how informed consent will be validated, i.e. Is the consent from the person who says it is?*
5. *How will consent be documented?*

Confidentiality

Confidentiality of sensitive data may not be as easily protected in Internet research as in more traditional research. "Cookies," small files often left on a user's hard drive, are sent back to the website each time a page is requested from a website. Cookies record computer information, details of links accessed, and even email addresses. Participants may be unaware that online interactions may be stored in the cache or the server's log files.

Researchers should provide the Committee with their plans for ensuring confidentiality of the data during the different stages of research (gathering, processing and storage). In addition, safeguards should be in place for protecting against inadvertent disclosure and deliberate attempts to gain access to the data.

Data transmitted via email is not anonymous; the sender's email address is contained in almost all email forms. Researchers may use a third party for stripping email addresses or develop screen warning messages, disclosing the limits of security.

NOTE: The School of Public Health archives all email messages.

*Points to address in the CHR application:*

1. *Will the survey contain identifiers or will it be anonymous? Will a third-party strip identifiers (email addresses)?*
2. *How will the data be transmitted to the server and what measures will be taken to ensure data security during transmission?*
3. *How will data be stored and secured?*

#### *4. What technical information will be given to subjects preceding online interactions?*

##### Website Content

The content of the information contained on a website or distributed to potential subjects must be reviewed and approved by the Committee. A hard copy of the information to be presented must be submitted with the CHR application, along with the website address.

##### Committee Review

The Federal regulations require that an institutional review board (IRB) have the professional competence, through experience, expertise and diversity of its members necessary to review specific research activities. In compliance with this requirement, the JHSPH Information Systems Administrator serves as technical consultant to the Committee when reviewing all Internet-based research involving human subjects. The technical consultant reviews the research design, with particular attention paid to issues of privacy and confidentiality.

All research may not be appropriate for the Internet and, therefore, may not be approved by the Committee.