NIMH
National Institute
of Mental Health

Internet-based Research Interventions: Suggestions for Minimizing Risk

This chart was developed by staff of the NIMH Division of Services and Intervention Research to help researchers anticipate and address challenges they may encounter during research studies of mental health interventions that use the Internet. This chart is not intended to be an exhaustive list of topics to consider and should not be construed as federally mandated law. Because technology is constantly changing, it is the investigators' responsibility to keep abreast of developments that will influence their Internet interventions and to educate research participants accordingly. While the chart is intended to provide some helpful guidance, it cannot replace the input and advice researchers must seek from a range of experts in technology, data security, privacy, and confidentiality related to research interventions using the Internet and the research participants involved. These experts should be part of the study's design to anticipate usability problems that may affect research participants' safety. NIMH will periodically review and update this chart as necessary.

Research Issues	Suggestions
A. Anonymity or false information of research participant; false information about research study.	
− The research participant may not provide accurate information about their identity (age, demographic background, minority status, diagnosis, etc.) Thus, vulnerable populations (e.g., children, prisoners, etc.) might not be adequately protected.	• Have face-to-face meeting with research volunteer. • Permit research participants to join with pseudonym (e.g., e-mail address). • Require research participants to provide identifying information (name, address, phone number) over Internet. • Verify address; send mail to research participants and require them to sign and return it to the investigator. • Verify phone number; call research participants at phone number they have provided. • Consider including only research participants who are already known as members of a specific population (e.g., HMO); give them an access code for identification purposes.
− Participants may repeatedly submit e-mails for study reimbursement and use different user names in the process.	• Ask basic demographic information twice. • Make reimbursement small relative to time commitment in study. • When reimbursement e-mails are close in time, check similarity of e-mails; check demographics of participants in closely submitted questionnaires; check passwords for similar traits; verify other contact person; cross-verify information taken during assessment, like age and birth date.

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Research Issues	Suggestions
B. Individuals posing as researchers may seek information from vulnerable persons.	• Provide research participants options for verifying the credentials of the researchers and approval of the study (e.g., Internet addresses, telephone, mailed information). • Use signed certificate and SSL (Secure Sockets Layer) for all data transfer over the Internet. • Provide participants with paper documentation about the nature of the research questions that will be asked, the Web address to which they will connect for the study, and the security signed certificate that will be used. Encourage participants to call the study center directly with any concerns and inform them not to answer any information outside the scope of the study, especially confidential financial information.
C. Limited monitoring of a research participant's clinical status over the Internet; the participant will not have immediate access to a treating clinician/facility in case of an emergency (e.g., suicidality). – The participant might assume that someone is monitoring his/her self-reported data on an immediate basis. He/she might expect that "cries for help," submitted over the Internet, will be seen and that an immediate response is forthcoming.	• Discuss, in advance, procedures that the participant should follow if symptoms worsen or if they face an emergency. Inform research participants whether they should contact someone from the study or if they should pursue a referral to an outside mental health practitioner. • Inform research participants how frequently the data will be checked and whether they will be evaluated for signs of clinical deterioration. • Consider providing a return receipt when messages are received by both research participants and researcher. • Include explicit questions that inquire whether a participant needs immediate crisis assistance, which can trigger direct notification of the researcher rather than simply recording and archiving the data for analysis.
– The investigator will have less accessibility to monitor participants' progress and possible deterioration than with in-person contact.	• In longitudinal studies, use participant's data to build baseline "risk" or "symptom level" profiles based on measures asked in Internet assessment sessions. Include profile threshold triggers that automatically bring the participant to the researcher's attention when the risk or symptom levels deteriorate to the threshold level. • Use adaptive questioning strategies by which screening questions for risk areas are followed up with more extensive questions if responses suggest problems. • Develop a plan for identifying research participants who experience clinical deterioration and how these research participants will be handled if their data reveal they are in crisis. • Before enrolling research participants, obtain information about how they can be contacted if they are in crisis. Ask participants to provide another person as an emergency contact.

Internet-based Research Interventions: Suggestions for Minimizing Risk (continued)

Research Issues	Suggestions
D. Lack of in-person communication between research participant and researcher. – Limited literacy and other disabilities might interfere with research participant's ability to understand information delivered via the Internet. This could affect both the ethics and methodological rigor of the study.	• Augment intervention with face-to-face discussions, home visits, and phone calls. • Include an evaluation of any participants with disabilities and make certain research participants understand how to use the computer program. • Do usability testing on the intervention to ensure all participants have access. Utilize graphics for limited literacy. • Include a readability assessment for all electronic documents. (Make sure this assessment is conducted for each conceptual unit.) • Offer audio narration in multiple languages. • Interventions should comply with federal disability standards for Web sites. (See http://www.section508.gov.)
– It could be difficult to contact research participants to notify them about their status in the study or to insure they receive adequate follow-up in the event of a clinical emergency.	• Determine, in advance, criteria for removing research participants from a study, procedures for contacting and informing them of this action, and a means for referring them to receive active treatment. • Have a plan in place concerning how research participants will be able to receive additional treatment if needed, especially if they lack medical insurance.
– Limited computer literacy/skills of research participants may hamper study.	• All research participants must understand how to use the technology involved in the study. Pre-training may be necessary to ensure participants can use the systems and understand them apart from informed consent.
– Online forums that are part of a study could increase the chance of participants' suicidal behavior or other deterioration ("flaming").	• Establish procedures to facilitate immediate response to each possible risk, including calling the police, a family member, or a subject's clinician. • Restrict access to the group and have study personnel monitor communications.
E. Limited information as to whether consent was informed. – The investigator might not know whether research participants comprehend important information about the study.	• Develop a questionnaire to assess research participants' understanding of important information over the Internet.
– No opportunity for research participants to ask questions about the study.	• Correspond with research participants and permit them to ask questions via e-mail or over the telephone.

– No opportunity for investigator to evaluate mental status by observing and interacting with the research participant. Difficult to assess research participants' capacity to consent.	• Assess capacity:
	  − over the Internet via research participant self-report;
	  − by interviewing caregivers;
	  − over the telephone; or
	  − in person.
	• Consider additional safeguards for high-risk or vulnerable groups, such as research participant advocates or a Data Safety Monitoring board.
	• Incorporate person-to-person review of "bookmarked" consent issues – questions volunteers have about particular consent issues.
	• Create a "Frequently Asked Questions" list for each consent issue to give to volunteers.

Internet-based Research Interventions: Suggestions for Minimizing Risk (continued)

Research Issues	Suggestions
F. Delay of appropriate treatment. – The research participant may avoid or delay seeking alternative efficacious treatments due to beliefs that the computer-based intervention will suffice.	• As in other intervention research trials, inform the research participant that the study is an experimental treatment and its effectiveness is not yet known. If effective treatments exist for the disorder being studied, research participants should be informed about them before entering the study. • Reinforce that online intervention may not necessarily be a substitute for usual care during face-to-face meetings.
G. Uncertainty regarding adequate debriefing. – At the end of the study, research participants are informed about the "condition" to which they were assigned (e.g., control or experimental). They could experience confusion, anger, etc. – If debriefed over the Internet, research participants' unanticipated negative reactions might not be observed and corrective measures might not be taken.	• Conduct debriefing: − over the Internet; − over the telephone; or − in person. • Develop self-report questionnaire evaluating research participants' reactions to this information. Provide the subject with additional information for phone contact, in-person contact, and/or referral or treatment, if necessary.
H. Unintended limits to privacy and confidentiality. – Participants and even investigators might not be aware of the limitations of Internet technology in assuring confidentiality of research participant data, e-mail, and other participant information. Research participants may assume that communications are confidential and are not recorded or stored.	• Consult with experts in technical aspects of securing information over the Internet. • Implement a data security plan, which should detail the server-side and client-side solution (i.e., software, network, and any required hardware) used in the intervention. This plan should be reviewed by an outside expert (a qualified person who did not design the software intervention). Institutional Review Boards may want to consider adding expertise in Internet security technology to provide adequate protection of research participants. • Utilize state-of-the art technologies, such as SSL data exchange, to maximize the protection of participant data, even when collecting data anonymously. • Protect all servers that house Internet interventions, both electronically and physically. • Do not store participant identifying information on the intervention Web site; do not allow users to use their real last names as log-in names; edit out any personal identifying information that a user posts on the Web site. • Include security cautions at the beginning of each user session to allow participants to implement security measures each time they log in. For example, provide a link from an open access Web page to a secure Web server (https) prior to log in.

Internet-based Research Interventions: Suggestions for Minimizing Risk (continued)

Research Issues	Suggestions
− Confidentiality may be breached when using a computer terminal in a public area such as a library or school setting.	• Inform research participants: – on how communications are recorded and stored; – that they too are also responsible for keeping their information private; – on the limits of data protection, even under the best security circumstances; – not to write anything in an (unsecure) e-mail they would not want other people to know about; and – that their own physical situation should be secure when they access the study Web site in public areas, such as library computer terminals.
I. Biased sample selection. − Access to computers is frequently determined by socioeconomic status, which may prohibit certain populations from participating (e.g., specific underserved ethnic groups, homeless persons).	• Be aware who the population of interest is; consider research to determine how different recruitment strategies can affect the sample before the intervention study.
− The burdens and benefits of research might not be equally distributed across ethnic groups and other minority populations.	• Provide training to instruct participants how to use the Internet and computers. Access to a computer is not comparable to comprehending and demonstrating technology skills.
− All types of accessibility barriers must be considered: physical, cultural, racial, and cognitive.	• Include funding to support accessibility to computers and the Internet and computer-essential equipment (e.g., printers, paper, ink cartridges) and maintenance, as necessary, or consider establishing an agreement with a local library, clinic, or government facility that would allow participants to use that facility's computer to access the intervention (e.g., through a Web site with a password).
− Results of research over the Internet might not be generalizable to these populations that do not have ready access to the Internet.	• Cast a wide recruitment net. Consider using the Internet to promote the study by submitting study information to major Web search engines and/or health and mental health constituent groups to post on their Web sites and discussion groups. Use traditional methods of recruitment used by non-Internet studies (e.g., newspaper and radio ads; feature articles in advocacy newsletters and community newspapers; brochures for community and outreach efforts; speakers at community forums).

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