Internet-based Research Interventions:

Risk Minimization Strategies*

Risk	Possible Procedures for Minimizing Risk
1. Anonymity or false information of research participant; false information about research study − The research participant may not provide accurate information about their identity. − Research participant may provide false information about their age, demographic background, minority status, diagnosis, etc. Thus, vulnerable populations (e.g., children, prisoners, etc.) might not be adequately protected. Also, the burdens and benefits of research might not be equally distributed across ethnic groups and other minority populations.	• 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. • Could include only research participants who are already known as members of a specific population (e.g., HMO), give them an access code for identification purposes.
2. 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., URL's, telephone, mailed information).

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3. Lack of in-person communication between research participant and provider. – The participant will not have immediate access to a treating clinician/facility in case of an emergency (e.g., suicidality).	• Discuss, in advance, procedures that the participant should follow if symptoms worsen or in case of an emergency. Inform research participant whether they should contact someone from the study or if they should pursue a referral to an outside mental health practitioner. • Information about these factors, including referral information could be placed on the web site itself, always accessible to the participants during the study.
– Research participants with literacy and other disabilities might interfere with their ability to understand some information. This could affect both the ethics and methodological rigor of the study.	• 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 assure maximal access by all persons. • Intervention should comply with disability standards for web sites (see http://www.section508.gov).
4. Limited monitoring of research participant's clinical status over the Internet. – 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 immediately responded to by a person reviewing the data.	• Inform research participants how frequently the data will be checked and whether these data will be evaluated for signs of clinical deterioration. • Consider providing a return receipt when messages are received by both research participants and researcher.

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– The investigator will have less accessibility to monitor participants' progress and possible deterioration than with in-person contact. – 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.	• Develop a plan for identifying research participants who experience clinical deterioration and how these research participants will be handled if their data reveals they are in crisis. • Before enrolling research participants obtain information about how they can be contacted if their data reveals they are in crisis. • Obtain name of another person as an emergency contact. • 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 in place a plan concerning how research participants will be able to receive additional treatment if needed, especially if they don't have medical insurance.

5. Limited information as to whether consent was informed.
 	
– The investigator might not know whether research participants comprehend important information about the study.
 	
– No opportunity for research participants to ask questions about the study.
 	
– No opportunity for investigator to evaluate mental status by observing and interacting with the research participant. Difficult to assess research participants' **capacity** to consent.
	• Develop a questionnaire to assess research participants' understanding of important information over the Internet.
	
	• Correspond and permit research participants to ask questions via e-mail or over the telephone.
	
	• Assess capacity:
	  – Over the Internet via research participant self-report
	  – By interviewing caregivers
	  – Over the telephone
	  – In person
	  – Consider additional safeguards for high-risk or vulnerable groups, such as research participant advocates or a Data Safety Monitoring board.

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6. 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.	• 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.

7. 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, referral or treatment, if necessary.

8. Unintended limits to privacy and confidentiality – Participants and even investigators might not be aware of 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. – Confidentiality may be breached when using a terminal in a public area such as a library or school setting.	• Need to educate themselves or consult with experts in technical aspects of securing information over the Internet. • Need to utilize state-of-the art technologies to maximize the protection of participant data. • Inform research participants of whether and how communications are recorded and stored**.** • Inform research participants about all avenues where breaches in confidentiality may occur.

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9. Biased sample selection – Access to computers is frequently determined by socioeconomic status, which may prohibit certain populations from participating (e.g., specific ethnic groups, homeless persons). – Results of research over the Internet might not be generalizable to these populations. They might not benefit from the results of such research.	• Include funding to support accessibility to computers and the Internet and computer-essential equipment (e.g., printers, paper, ink cartridges) and maintenance, as necessary, for persons with limited resources. • Recruitment efforts could be aimed at persons who might not usually have access to computers.

* Developed by NIMH staff as a result of the workshop "Consider This: Cyber Interventions in Mental Health – Ethical Considerations" held November 3, 2000.