Guidelines and Recommendations for Remote Individual Interviews and Focus or Discussion Groups

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Institutional Committee for the Protection of Human Subjects in Research (CIPSHI)

Physical distancing measures to prevent the spread of COVID-19 have posed new challenges to researchers with research projects that use methods for data collection through face-to-face interaction with study participants or subjects. CIPSHI has outlined guidelines and recommendations so that protocols be adapted for the remote data collection alternative—whether it be initial protocols or through modifications[1] to previously authorized protocols.

Although some of these guidelines do constitute current CIPSHI requirements, others are recommendations or considerations that researchers should take into account when presenting their research protocols and creating the research instruments, the documents for informed consent and data protection.

A. Tools

1. The use of **virtual tools** is a viable option if, as a researcher, you believe this data collection method would not adversely impact the objectives proposed in your research. Although CIPSHI does not currently require the use of any specific tool or platform for individual or group interviews (e.g., focus or discussion groups), we recommend you use the institutional platforms (Google Suite or Microsoft Teams). The use of these tools through the **@upr.edu** domain offers researchers the possibility of greater technical assistance, if required. Additionally, both Google Suite and Microsoft Teams meet the required HIPAA specifications for health information exchanges, which offers greater security for the management of the information collected. However, CIPSHI is acknowledges that there are other tools with features more closely related to the needs of each study.

[1] The modification request form can be found in CISHI's website as "Authorized Protocol Modification Request Form": http://graduados.uprrp.edu/index.php?option=com_content&view=article&id=169&Itemid=430&lang=es.

2. Examine and verify the data privacy and storage policies of the selected tool. Remember you must inform potential participants of the possibility of third parties—who are not part of the key research personnel or affiliated with the research—accessing the data.

3. Learn how to use the tool and its features. You must have the knowledge to instruct participants on its use before and during the individual or group interview. You must also know who can make recordings and save the data; whether only the researcher will have access to this feature or if any user can do it. Select a tool that allows you to monitor, control and delete the option to allow participants to record audio or video. This increases the security levels of the information collected. If this is not possible, you must specify this limit to confidentiality in the instructions for using the tool and in the informed consent form.

   In addition, you must instruct on how to turn on and off the cameras and microphones, as well as how to log out and exit the platform before and during the interview. If the person does not correctly log out of the platform, the session may stay active and continue broadcasting information that may be recorded in audio or video. Once finished with data collection, verify that everyone has logged out.

4. If the use of the tool implies that the person will incur any additional costs to be able to participate in the research, this must also be disclosed. Expenses are not only related to the purchase of applications, there may also be additional charges for mobile data consumption, internet connection or storage on the person's devices.

5. You are responsible of taking the necessary precautions to prevent unauthorized access or interception when storing or transferring participants' data via the internet. Keep in mind that data stored both on the cloud (Google Drive, One Drive, Dropbox, etc.) and on physical devices must be protected by at least one strong password. In addition, keep in mind that data must be handled and used in accordance to what is stipulated in the protocol and what was agreed with the participants.

B. Process for Individual Interviews and Focus or Discussion Groups

1. Write **specific and clear instructions** for using the virtual tool as well as for any necessary accessories (camera, microphone, etc.). The instructions must be at an understandable level depending on the age, school level and knowledge of technology of the potential participants. Include how you will proceed if there is an

interruption in communication. You must send the instructions in advance using the agreed on communication channel.

2. **Contact** potential participants individually **before** the process. By doing so, you will be able to discuss informed consent as well as instructions for using the tool and directions for the interactions in the individual or group interviews.

3. Verify that the person has a **safe and private space** during the scheduled time. Respect that schedule unless the person gives authorization for the session to be extended. As a researcher, you must also guarantee these conditions as well as be in an environment free of interruptions and in which it is not possible for third parties to listen to the conversation or to observe the screen with the participants' transmission.

4. At the beginning of the process, **revisit the instructions** for using the tool—including the microphone and camera, audio or video recordings and other pre-agreed conditions. Participants must be clear about whether the interview will be recorder or not, and if so, whether only the audio or also video will be recorded. Note that even if the person has their camera turned off, their real name or their username may appear and be recorded.

   If you work with **groups** and each individual has the option to choose between being recorded with video or audio only, instruct them on how to turn off the camera.

   For **groups**, remind participants about the limits to confidentiality and urge them to not record or disclose shared information.

5. To facilitate understanding, consider sharing the **screen** with the documents, questions or discussion points for the consent taking, instructions and interview session with participants.

6. If the research is on sensitive or clinical topics or involves other risks that merit it, develop a **protocol for emergencies or incident handling** that also takes into account if there is an interruption in communication. You must specify (a) how the person will be treated or referred to the pertinent services, (b) alternative forms of communication such as phone calls or physical visits, (c) that the relevant authorities and the participant's family member or contact person will be notified, etc. To this purpose, you must obtain the participant's contact information—including their phone number and, depending on the risks or type of intervention, their physical address and contact information of a family member or close person. In addition, you may need to get information about who their health care provider is (physician or mental health professional).

You must discuss this protocol with the potential participant as part of the informed consent process and before starting data collection.

7. Write down the **date and time** of all interactions with the participants.

C. Informed Consent Process

1. If you are going to use a standard informed consent form that requires the signature of the participant, explain how you will do this and whether you will require the person to have resources or applications to process a digital signature or scan and send the signed document.

2. If obtaining a consent form signed by the participant is not possible, request a **waiver** to modify the standard process for obtaining consent. This waives the requirement for signatures and replaces the standard informed consent form with an information sheet.

   However, you must specify how you will confirm or document that the person consents to participate in the interview, especially if it will be recorded or if you will disclose identifiable information. An alternative is to record the person's authorization as part of the recorded interview (audio or video), as well as their confirmation of receiving and discussing the information on the consent form. Guide the consent-taking process with questions like:
   - Did you understand what I just explained to you?
   - Do you have any questions or concerns?
   - Are you okay with participating in this study and having us record the audio or video?

   Participants may also request a consent document signed by both parties. In this case, the researcher must honor their decision.

   CIPSHI will evaluate the waiver requests and will grant them according to the criteria established in federal regulation 45.CFR.46.

3. Consider the time it will take to get the informed consent, discuss the instructions on the use of the tool, as well as the necessary tests to establish communication as part of the approximated time it will take the person to participate in the study.

D. Informed Consent Form

In addition to the standard elements required by CIPSHI and the additional considerations depending on the particularities of the research, consent sheets for remote interviews must contain the following elements:

1. In the section on risks or discomforts:

    a. State if the person is required to download any application or program and whether it entails any cost; or if the person may use their preferred means of communication.

    b. State that there may be additional fees for the consumption of mobile data or internet connection.

    c. Notify of the possible inconvenience of learning to use the tool, as well as the possibility of exhaustion from using the tool. Discuss with your potential participants whether they prefer to segment the interview into one or two one-hour slots or any other time frame you want to set.

    d. If applicable, inform the participant of the protocol for emergencies or handling of any incident that must be addressed, including referrals to the relevant services.

2. In the section on confidentiality:

    a. Note that research with transfer of information over the internet, recordings, and interaction between participants **is not anonymous**. Distinguish between confidential data handling and how you will disclose results. Meaning whether you will be publishing data with identifiable information or publishing it anonymously.

    b. Include the following warning: *The information you share electronically on the device (computer, cellphone or other) or platform you use may be tapped or reviewed by third parties. These individuals may have legitimate or illegitimate access to the device and its content; like a family member, employer, hackers or intruders, etc. In addition, the device you use may keep track of the information you access or send electronically.*

    c. Clause for group interviews or focus groups only:

    As the information will be shared between participants, indicate that you cannot guarantee that the information shared in the group will not be disclosed by the

participants. Encourage your participants to keep information confidential and not to record the session.

3. In the section on rights:

   a. When explaining the voluntary nature of participation, instruct on how to terminate participation or log out of the platform upon finishing the interview.

   b. When informing the person that they have the right to receive a copy of the consent form, add a note exhorting participants to save or print the consent document.

4. Participation alternatives:

   Before the fields for signature or confirmation, add check boxes corresponding to what is optional (e.g., video or audio recording, disclosure of identity, etc.).

E. Training - CITI Program

We recommend you read or revise the module on Internet Use that can be found in the CITI Program's training on research with human subjects (https://about.citiprogram.org). The module (titled "Internet-Based Research) can be found in the English version of the "Human Subjects Research" course.
Instructions for registering for the CITI program and how to identify the course can be found on CIPSHI's website under "CITI Program.