

This guidance reviews the best practices for performing research remotely with human subjects (or participants). The information outlines considerations for protecting participants' privacy and confidentiality. For questions, additional information, or support with this document, please contact us at <u>irb@ucr.edu</u>. This document is not meant to cover all ethical issues but provide a primer on key topics and ethical issues on fully remote or hybrid research.

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Preparing to Work Remotely

Preparing the Research Team

- Develop a communication plan for the research team. Ensure personnel know whom to contact if problems or concerns arise with the study
- Verify that the research team have the resources and information necessary to carry out study activities and ensure privacy and confidentiality
- Establish research team policy and guidance related to privacy, confidentiality, and data security. Research team-specific policy may include instituting confidentiality agreements, logs to check out/in physical files, creating guidance in case of a confidentiality breach, etc.
 - Please note: Confidentiality breaches of human subject data should be reported promptly to the IRB (within 10 working days) using the <u>Event Report Form</u>
- Develop standard procedures to address privacy concerns that may arise during study activities (e.g., interruptions during virtual interviews/focus groups)
- Confirm that data/records/equipment/supplies are permitted to be taken/accessed off-campus, and where they will be stored during that time. The ISO can assist with this.
- Research Computing should assist in providing recommendations for storage and use of this data off campus.
- Ensure with assistance of the ISO the appropriate <u>UC classification level</u> and level of protection to be used for the data.
 - Sensitive, identifiable data must be protected using encryption software along with any other appropriate controls based on classification level.
- If you are doing sponsored research (e.g., NIH, NSF, DoD), ensure you are following the sponsor's data protection requirements. ISO and Research Computing can assist with the creation of a Data Security Plan which is designed for this purpose.
- If you are doing international research, make sure that you have all the **Export Control** approvals needed
- Be vigilant of any cyber security threats. If you have any concerns, contact infosecoffice@ucr.edu.
- For questions or consultation regarding data management or computing resources available, contact <u>research-computing@ucr.edu</u>.

IRB Application: Approvals and Amendments

• Ensure that IRB approval has been obtained for the study. The approved IRB application should clearly describe that study procedures are occurring remotely. If your IRB application indicates that processes will only occur in-person, it should be amended to note that these processes may take place remotely.

Best Practices for Working Remotely -Human Subjects Research



- If needed, submit an <u>Amendment Request form</u> to include the remote procedures to <u>irb@ucr.edu</u> for review and approval prior to implementation. Include all necessary study changes in the amendment request. Common modifications involve those to measures/questionnaires, consent processes, data collection methods (including virtual platforms used), and compensation methods (e.g., e-gift card).
- All amendment requests require IRB approval prior to implementation of the new procedures; however, federal regulations all PIs to deviate from IRB approved procedures for the removal of an "immediate hazard" to participants. For example, transition from in-person study visits to virtual visits to eliminate the risk of participants contracting a pandemic disease (e.g., COVID-19).
 - Changes unrelated to addressing the "immediate hazard" must be submitted through the amendment request process. These changes may include:
 - Recruiting/enrolling a new participant population
 - Adding new measures, questionnaires, etc.
 - Incorporating procedures that increase the risk of the existing study
 - Any deviations resulting from eliminating an "immediate hazard" must be reported to the IRB following cessation of the emergency. Researchers must complete the <u>Event Report Form</u> and submit to <u>irb@ucr.edu</u>.

Special Considerations: Remote Informed Consent Procedures

- Determine the Informed Consent process you will use which provides a mechanism for participants to consent remotely. This process may not utilize the standard signed (hardcopy) consent form; however, the IRB may approve waivers of documentation of consent in certain situations and an alternative method is used to document consent in lieu of a signature (e.g., verbal consent).
- Informed consent processes include:
 - Wet signature The traditional pen and paper signature. Researchers should consider the possible barriers in getting the form to the participants (e.g., via regular mail or email) and how the hardcopy will be returned back to the researchers. Researchers should consider the technological capacity required if asked to print, scan and email a signed form back the researchers.
 - Electronic signature An "electronic signature" is an electronic sound, symbol, or process, attached to or logically associated with an electronic record or adopted by a person with the intent to sign a record. For use of electronic signatures, the IRB will consider such issues as how the electronic signature is created, if the signature can be shown to be legitimate, and if the consent document can be produced in hard copy for review by the potential subject. If properly obtained, an electronic signature can be considered 'original' for the purposes of recordkeeping. For FDA-regulated research, "electronic" documents would be subject to a specialized set of requirements found at <u>21 CFR Part 11.</u>
 - Verbal consent Consent is provided by the participant's oral acknowledgement to participate in the study. This process would likely be the most feasible when conducting interviews or focus groups. Researchers should consider distributing the consent form to all potential participants beforehand, allowing them time to review the document on their own. Use of this process in research requires a waiver of documented consent approval by the IRB.
 - Online Consent For web-based surveys or questionnaires, the consent form may be presented online, and require participants to perform some action, such as clicking "I agree," before proceeding with any research activities (e.g., answering survey questions on a website). This is an acceptable approach for low-risk research conducted online. However, be aware that this method does not document informed consent, and therefore, use of this process requires a waiver of documented consent by the IRB.



Special Considerations: Remote Digital Recordings Procedures

- Determine in advance whether audio and/or video recordings will be required for participation in the study, and make that explicitly clear to participants.
 - If recording is optional, the informed consent document / script should have a separate section where participants can consent or decline to the recording.
 - Participants must provide consent to audio and/or video recording.
 - Have a plan in place for those who consented, then changed their mind.

Technological Considerations

- Determine the technology you will use for the data collection activity and how you will record the conversation (if applicable). Things to consider when selecting technology include:
 - For interviews, whether a phone call is sufficient, and the added value, if any, of a video call. Consider providing participants with the option to join via phone or video based on their preference.
 - The technological capacity required of participants to complete a phone vs. a video interview
 - The technological capacity required of participants to engage in a focus group via videoconference and whether individual phone or video interviews may be better received
 - Researchers should be mindful of the barriers to connecting via videoconference, such as broadband or mobile data coverage and access to a computer or smartphone, and how these barriers may disproportionately affect particular populations who experience socioeconomic disparities (e.g., rural, low-income)
 - Additionally, researchers should be mindful of the capacity of the participant population to use the selected technology. For example, participants who are much younger in age or who have a cognitive impairment may not be able to utilize Zoom without assistance on their end
- Two resources that are commonly used by UCR researchers doing remote work are Zoom for videoconferencing and Qualtrics for online surveys. Both platforms are available to UCR faculty, staff, and students free of charge.
 - Zoom for videoconferencing: <u>https://ucrsupport.service-</u> <u>now.com/ucr_portal/?id=kb_article&sys_id=eba05e481bda4050453e7592cd4bcbea</u>
 - Qualtrics for online surveys: <u>https://sitelicense.ucr.edu/qualtrics.html</u>
- Take steps to enhance security of videoconference sessions, such as provide participants with a password for joining the call.
 - When using Zoom, increase meeting security by:
 - Making meetings private
 - Creating a unique meeting ID for each meeting
 - Disabling the ability for local recording (both video and chat messaging)
 - Waiting until just before the session to share meeting details with participants
 - Sending meeting links and information directly to participants (not posting online)
 - Using the Waiting Room feature, where the host manually admits participants into the session: <u>https://support.zoom.us/hc/en-us/articles/115000332726-Waiting- Room</u>
 - Requiring a password to enter the session: <u>https://support.zoom.us/hc/en-us/articles/360033559832-Meeting-and-Webinar-Passwords-</u>
 - Disable join before host
 - Once all participants have entered the meeting, consider locking the meeting
- Recording options include using speakerphone (in a private area) and recording with a standard digital recorder, recording directly via phone, attaching a recording device to the phone, or using a videoconference platform that allows for recording.



- If recording directly on a videoconferencing platform:
 - The recording files may include both an audio and a video file. If you do not need
 a recording of the participant's face, you can ask the participants to call in to teleconference
 (instead of joining online) or turn off cameras before recording.
 - Disable participant recording options for online focus groups to help promote confidentiality.
 - For more information on setting up and managing local recording via Zoom, see: <u>https://support.zoom.us/hc/en-us/articles/201362473#h_3a53d485-a50f-4f6a-8019-533a0526fe47</u>

Practice!

- Practice using the technology by having a few mock interviews or focus groups discussions before you begin data collection, and test your recording settings and technology in advance with members of your research team and co-investigators.
- Additional tips for conducting remote research can be found on UCR's <u>COVID-19 Guidance for Human Subjects</u>
 <u>Research</u>
- Review the remote resources available to UCR researchers via:
 - <u>https://keepworking.ucr.edu/</u>
 - <u>https://keepresearching.ucr.edu/</u>
- Use video tutorials to familiarize yourself with Zoom. A library of *How To* videos from UCR faculty are available and can be found here:

https://www.youtube.com/channel/UCxC1CHd3QavcVrT8I8VONAQ/videos

- Some helpful topics are listed and directly linked below:
 - How To Set All the Zoom Preferences to be what you want: <u>https://www.youtube.com/watch?v=loy3v9qq2YA</u>
 - How to Set Up your Home Lighting: <u>https://www.youtube.com/watch?v=mmNIQ_ckh8U&feature=emb_logo</u>
 - How to Use Breakout Rooms in Zoom: <u>https://www.youtube.com/watch?v=PrKMdJZ9ci4</u>
 - How Do I Lock Down My Chat in Zoom: <u>https://www.youtube.com/watch?v=Ja69mvq1yk0</u>

Preparing Participants

- Communicate with participants in advance so they know what to expect when engaging in remote research activities. If they are unfamiliar with videoconferencing, you may choose to send UCR's <u>Zoom</u> <u>Attendee guide</u>.
- During the recruitment process:
 - Let participants know if audio/video recording is mandatory for participation (e.g., an online focus group which requires the discussion to be recorded).
 - Ask participants about their internet access, if that is a requirement to participate. If possible, have a phone option available for those who do not have stable internet access.
 - If possible, ask participants to join videoconferences from a secure internet connection (i.e., not public Wi-Fi).
 - Ask participants to call from a private location where there will be few interruptions; however, be aware that this may be difficult for some participants, such as parents at home with young children or those living in high-density homes.
 - Inform participants of steps they can take to protect their privacy (e.g., closing their web browser after survey completion, avoid using shared devices, finding a private location to complete interviews, etc.)



- If conducting an online focus group, communicate any risks unique to an online environment, such as potential risks to confidentiality (e.g., others in the focus group not having a secure internet connection, others in the focus group not being alone or in a secure location).
- If using videoconference software, provide participants with tutorials or technical support in advance, including written instructions for joining the videoconference. If possible, allow phone as a backup option. Understand that participants' technological literacy will vary, and be willing and available to answer questions.
- If applicable, let participants know when / how compensation will take place (e.g., e-gift card, emailed to them after completion of the session).

Data Collection Activities

Conducting Remote Interviews

- Take the call from a private room with no distractions. If using online software, join from a secure Internet connection (i.e., not public Wi-Fi)
- At the beginning of the call:
 - Introduce yourself and the project (this helps with building rapport, particularly when the participant has not met you in person)
 - \circ $\;$ Ask participants if it is a good time; suggest that they find a private place to talk
 - If possible, summarize a brief consent and remind participants that they can end the interview at any time or chose not to answer any questions. It's always a good idea to tell participants at what point they will no longer be able to withdraw their data during the consent.
 - Ask participants to tell you what they understand will happen in the study to them after you have completed the consent process and they have agreed to participate as a way to check their understanding
- Let the participant know when you will begin recording. State the date and time at the beginning of the recording.
- When you and the participant cannot see each other (e.g., via phone interviews), verbal probing and feedback is especially important
 - Communicate interest and attention verbally, using techniques such as:
 - Verbal probes (e.g., "Mmhmm", "Tell me more")
 - Reflective listening
 - Thanking the participant for sharing their experiences and perspectives
 - Pause and give participants time to respond. If you both speak at the same time, apologize and ask the participant to continue.
- If the participant appears distracted or distressed, offer them the opportunity to take a break
- If there is background noise, offer to pause the interview while they attend to the issue
- Videoconference platforms that allow screen sharing can be very helpful for usability testing interviews. For example, you can ask participants to share their screen as they navigate through a website or tool. Note that there can be a steep learning curve with using some of these features be prepared to walk participants through the process.
 - Instructions for accessing these feature in Zoom is available here: <u>https://support.zoom.us/hc/en-us/articles/201362153Sharing-your-screen</u>

Conducting Remote Focus Groups (FG)

- Join the session from a private room with no distractions. Use a secure Internet connection (e.g., not public Wi-Fi)
- Consider conducting the consenting process individually in advance, such as during the recruitment call
- If possible, aim for adequate staffing during the FG. This includes:



- A facilitator
- A note taker
- Consider having a third staff person available to provide technical support to participants if needed
- If appropriate, prior to admitting participants into the meeting session, consider re-naming the participants to pseudonyms to promote confidentiality during the FG.
- At the beginning of the session:
 - Offer a brief tutorial on how to use the online platform. Provide instructions for turning participant cameras on or off per their preference.
 - Go over ground rules, including how to take turns speaking [e.g., raising a (virtual) hand and waiting to be unmuted]. It's always a good idea to tell participants at what point they will no longer be able to withdraw their data.
 - Remind participants about the importance of confidentiality, and that they are each responsible for taking precautions to protect the privacy of fellow participants
 - Ask that they participate from a private room. Participants should be mindful about location to prevent roommates/family members/public from easily overhearing/seeing other participants.
 - Ask that they do not record or take screenshots of the session
 - Remind the participants of limits to confidentiality in focus groups of any nature
 - Let participants know when you will begin recording. State the date and time at the beginning of the recording.
- Pay attention to who is speaking and provide opportunities for all participants to share experiences. If some participants are more active than others, ask, "Would someone who hasn't shared yet like to speak?"
- Teleconferencing software often provides a variety of features for managing participant interactions during a group meeting. Familiarize yourself with these features ahead of time.
 - Information on managing participants in Zoom can be found at: <u>https://support.zoom.us/hc/en-us/articles/115005759423-Managing-participants-in-a-meeting</u>
- Consider whether using videoconference tools would support your discussion. Note that for participants new to videoconference technology, these tools may be a distraction or barrier to participation.
 - Examples of these tools in Zoom and ideas for their use include:
 - Whiteboard -- https://support.zoom.us/hc/en-us/articles/205677665-Sharing-a- whiteboard
 - Summarizing: Record participant responses on the white board and ask them to confirm or discuss
 - Brainstorming: Ask participants to write responses directly on the whiteboard.
 - o Screen share https://support.zoom.us/hc/en-us/articles/201362153-Sharing-your- screen
 - Share materials and ask participants to react/provide feedback
 - Demo a website or tool and ask participants to provide feedback
 - o Poll https://support.zoom.us/hc/en-us/articles/213756303-Polling-for-Meetings
 - Collect demographic information
 - Solicit initial reactions to a question and then discuss responses
 - Reactions https://support.zoom.us/hc/en-us/articles/360038311212- Meeting-reactions
 - Ask participants to indicate agreement or disagreement using the thumbs up/ thumbs down feature
 - o Chat https://support.zoom.us/hc/en-us/articles/203650445-In-Meeting-Chat
 - Ask participants to write responses to a question via chat, followed by discussion.
 Save the chat thread to refer to after the session.
 - Troubleshoot individual technical issues via chat