



“STARTER TOOL-KIT”
HUMAN SUBJECTS RESEARCH & FIELDWORK IN THE TIMES OF
COVID-19: MOVING FROM IN-PERSON TO REMOTE APPROACHES
(updated 5/8/20)

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INTRODUCTION

Isolation policies and measures to contain the spread of COVID-19 mean there are restrictions on research that involves direct, in-person human interactions or public observations [see FAQs posted on the [COVID-19 Research Operations website](#), which is updated regularly]. Some of these restrictions may remain in place for some time, as local/state and national efforts proceed to create accessible testing, vaccines, therapeutics to ensure that we can support public health and avoid upticks in virus spread as we bring the public back together.

Some researchers, as a short-term measure, have paused active or planned data collections with human subjects to focus effort on other critical activities that still move their research programs forward. These efforts include data analysis, grant proposal and manuscript/book writing, literature reviews, etc. But the COVID-19 situation has the potential to affect direct-contact human subjects and field research through the summer and into the coming academic year, at least.

As such, we encourage researchers to think of this time as an opportunity to consider different ways of engaging human subjects and field research - in ways that are rigorous and appropriate to their topics and questions, phenomena, and processes of study. For some, this might include considering if and how to transition some in-person human subjects research/fieldwork activities to those that do not require direct, in-person contact, such as online/virtual or technology-assisted approaches.

The use of remote human subjects/field research approaches is not new. For example, it is not uncommon for researchers to use online survey tools, conduct interviews by phone or audio/video-conferencing, and do content analyses or ethnographies using existing online interactions as research materials. Indeed, many U-M researchers have been able to continue their human subjects research because their study methods already did not involve direct, in-person contact. As such, we already have vast campus experience and expertise on a variety of online/virtual study methods.

To support our U-M research community, especially those who may be newly considering these approaches, we provide this document, a “starter tool-kit” which brings together considerations, information, and example resources used or recommended by our institutional IRB, individual researchers, and professional/disciplinary societies.

This document is by no means complete and comprehensive. Our goal is to use it as a starting point and continue to engage with our research community more systematically to learn about and help support human subjects research and field work needs.

So, we also invite YOU to share with us topics you wish to know more about (among those listed in this document and beyond), topics around which you'd be excited and willing to connect and share expertise with colleagues, and scholarly resources that you have found useful in your fields/disciplines:

- ***Quick Survey for U-M Researchers: Remote Human Subjects Research and Fieldwork Interests and Needs in the Context of COVID-19:***
https://docs.google.com/forms/d/e/1FAIpQLSeNtt-3-qKw9UaGKljSTr1ppeAyiE2x9W9prUHM2Cf8KcljZg/viewform?usp=sf_link
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“STARTER TOOL-KIT”: GENERAL CONSIDERATIONS

General Information: Restrictions and Allowances for Human Subjects Research

What is meant by the pause in human subjects research? What types of activities are restricted? What types of activities can continue? What is the process for approval for project modifications that adhere to restrictions policy?

- See: [COVID-19 Research Operations](#) - Research Involving Human Subjects FAQs (U-M Office of Research)
- See: [COVID-19-IRB-HSBSGuidance on the Research Pause](#)
- See: Michigan Medicine’s recommended [list of activities](#) for research staff during remote work assignment periods

General Best Practices for Conducting Research Activities Remotely/at home

Protecting participant privacy:

- IRB Recommendations: [Best Practices when Working Remotely with Human Subjects Information and Research Data](#)
- American Psychological Association: [Conducting research during the COVID-19 Pandemic](#)

Ethics and Responsible Conduct Issues in Human Subjects Research and Scholarship

IRB endorsed general resources

- [Human Research Protection Program \(HRPP\) Educational Resources](#) page provides link resources including:
 - o [PEERRS Human Subjects Module](#)
 - o [Good Clinical Practice \(GCP\) training](#) **required** for NIH-funded clinical trials
 - o [University of Michigan IRB Collaborative \(U-MIC\) modules](#) - brief video or slides with voiceover developed by the IRBs
 - o [CITI Program](#) educational resources
- HHS Office of Human Research Protections (OHRP) [Educational Videos](#) and [Information for Research Participants](#) provide an overview of the key concepts of human subjects protections
- [MICHR Education and Training Resources](#)

World Health Organization (WHO) guidance on behavioral studies related to COVID-19

- [SURVEY TOOL AND GUIDANCE](#)

Ethics of moving to from in-person to remote approaches during COVID-19 times

- Researchers should consider the emotional/affective environment when conducting any type of human subjects research, when normal routines are disrupted and many people are feeling uncertain and anxious, or are ill or caring for ill family members. People may be living in environments where they are subjected to surveillance, harassment, or violence by others (e.g., family members, partners, etc). Privacy issues are especially critical to consider in these contexts. On the other hand, with people more confined, feeling bored or restless but in good health, some may welcome the opportunity to be part of a research project. *Consider your target participants very carefully when making decisions about the best way forward, including weighing the research benefits in the context of participant benefits and costs during this unprecedented time. If proceeding, build in extra flexibility to accommodate and support participants.*
- Researchers also might look to guidance from their professional/disciplinary communities around ethical considerations that may be particularly relevant for their fields/topics/areas of research.:

Starter Tool-Kit: Remote HS Research in the Context of COVID-19

- o e.g., [Key ethical questions for research during the COVID-19 pandemic](#) (Lancet article on mental health research)
- o e.g., [Carrying out qualitative research under lockdown – Practical and ethical considerations](#)

CROSS-CUTTING TOPICS

Consent

Best practices for remote consent:

- A signed consent form is not necessary for many minimal risk research projects, particularly for online surveys or phone or videoconference interviews or other remote interactions. Investigators must provide participants with the required informed consent information but can request that the IRB issue a waiver of documentation of informed consent. The participant can give verbal consent which may be captured as part of an interview recording or indicate agreement to participate by clicking to the next page in the survey.
- For some projects that require signed consent, participants may be able to return a signed document to the study team via a scanned document attached to an email, a text of a photograph of the signed consent or via fax. Because [email](#) is not secure, these methods should be used only for research projects where the consent document does not disclose sensitive information about the participant.
- SignNow is a new HIPAA and FDA 21 CFR Part 11 compliant electronic signature tool. For more information and instructions for using this tool, see the [IRBMED Informed Consent](#) webpage.

Recruitment

Available databases for local, state, and national samples: e.g., how to locate and/or recruit study samples with particular characteristics, such as health profiles, community/family characteristics, sociodemographic backgrounds, etc.:

- Michigan Medicine's [Data Direct](#) offers cohort discovery tools that can be used to identify potential research participants and offers assistance in sending recruitment emails that do not disclose Protected Health Information to investigators.
- MICHR supports researchers looking to use UMHealthResearch to recruit participants for COVID-19 related studies; please see its [study teams page](#) or seek further guidance [here](#).
- [Qualtrics](#) and [KnowledgePanels](#) (formerly Knowledge Networks) maintain existing panels of survey respondents that may be used to target surveys to particular populations.
- [mTurk](#) is a resource developed by Amazon to recruit "workers" for tasks including taking surveys or other activities for research purposes. Recruitment can be targeted. Best used for recruitment rather than data collection since the mTurk worker ID can be linked back to an individual. A third-party product, [TurkPrime](#) provides the option for researchers to collect data through mTurk so that it is not linked to the worker ID.

Electronic Resources Generally

What kinds of hardware does the study team have to collect data remotely? Does the study team have laptops, tablets, smartphones, etc. that are properly equipped and secured for remote data collection?

- Investigators should consult the [ITS Sensitive Data Guide](#) regarding use of electronic resources. This Guide provides information to investigators on resources that have been evaluated by ITS and have been identified as secure or not secure for use with certain types of information. The University has not evaluated resources that are not listed, but investigators can consult with their [Security Unit Liaison](#) (SUL) to request an assessment of a resource that is not on the list.

Audio-/Video-Conferencing Software

Pros and cons of different platforms for different purposes:

- Some resources may be secure for conducting interviews and focus groups but not for recording interactions, so please confirm this before use.

Software use outside of U-M approved/licensed platforms:

- should not be used without evaluation by [Information Assurance](#)

Supports for HIPAA compliant video-conferencing

- [BlueJeans](#)
- [Zoom for Health](#)

Considering Accessibility

- Remote interaction software can be very useful, but not every platform is equally accessible to those who are deaf/hard of hearing or trying to function in a noisy household. The Institute for Social Research Accessibility Subcommittee has investigated three commonly used programs--Google Meet, Zoom, and BlueJeans--and offers the following guidance.
 - *Google Meet:* Real-time, fairly accurate automatic captioning make this the most cost-effective, accessible choice. It has a video meeting limit of 25. Captions cannot be saved. Look for the "turn on captions" control where you turn on the microphone and camera. (Note: There's a [Chrome extension](#) that enables a "Zoom-like" grid display of participants.)
 - *Zoom:* No real-time automatic captioning, but this program does allow for someone to provide fee-based, live captioning services. Those captions can be saved with the video.
 - *BlueJeans:* According to ITS (as of 3/18/2020), "Closed captions are not yet widely available to campus users of BlueJeans. The feature is available in a pilot format in Bluejeans to those who express a need for this functionality. ITS is working with BlueJeans to open this pilot to students, faculty, or staff who may need the functionality."

Survey Software

Pros and cons of different platforms for different purposes

- [Qualtrics](#) provides the option of collecting survey data without identifiers and provides an option that allows collecting contact information for compensation purposes without linking the data

HIPAA compliance issues when using survey software

- o [REDcap](#) as HIPAA-compliant software (available to Michigan Medicine)

Software use outside of U-M approved/licensed platforms of Qualtrics (all campus) and Redcap (Michigan Medicine)

- Any software outside of U-M approved tools, including software tools created in house should be evaluated by Information Assurance for data confidentiality and security practices. Procurement may require the vendor to sign a Data Protection Agreement (DPA).

Use of Apps (or similar online tools)

When considering apps or other online tools, e.g., for use in research involving interviews, group discussions, diary/journaling methods, among other approaches:

- Researchers must be aware of the terms of use for the app and the data being collected by the company providing the app or tool to ensure confidentiality of subject data. Some tools may

include "hold harmless" terms that are inconsistent with the prohibition of exculpatory language in informed consent. Please review platform policies carefully.

Considering Diversity, Equity, and Inclusion (DEI) when moving to remote human subjects research approaches

During the COVID-19 crisis, it is even more important to uphold our U-M values of diversity, equity, and inclusion. This includes close attention to DEI issues related to research.

Under what circumstances could remote approaches enhance diversity, equity, and/or inclusion? How could such approaches enhance the quality or impacts of your research or intervention?

- Researchers might consider how use of online/virtual approaches might broaden study or intervention participation opportunities.
 - o This might include, for example, reaching communities/participant pools that would otherwise be challenging to reach due to travel/mobility limitations. In some cases, virtual approaches could allow for more representative samples than would be achieved otherwise, positively impacting equity and quality.

Under what circumstances could remote approaches create barriers to diversity, equity, and/or inclusion? How could such approaches constrain the quality or impacts of your research or intervention?

- Researchers may have to weigh the benefits of continued research using online/virtual approaches with potential barriers to study/intervention participation opportunities.
 - o For example, access to reliable wifi/internet, private computers/tablets/devices, and/or private spaces for study participation may be challenging for some prospective participants/communities. There may be ways to mitigate some barriers (e.g., flexibility in scheduling participants based on their technology access, availability, and privacy needs; asynchronous interaction approaches) but not for all cases. [But, as sample representativeness is a common issue in all research (regardless of pandemics!), plan to engage in good research practice by documenting and reporting how your study approach may have impacted participation and representation.]

Accessibility Considerations with Remote Research Methods

- (see above section on "Audio-/Video-Conferencing Software")

Opportunities and Challenges of Online Human Subjects Research (Scholarly, Ethical, and DEI Considerations)

- Example: [Report from the American Psychological Association Board of Scientific Affairs on Internet Research](#)

COVID-19 and DEI Research

- Some researchers have begun to investigate how the current COVID-19 pandemic has illuminated and/or stimulated attitudes and behaviors of xenophobia, racism, and bias. Developing knowledge about these types of issues is important to fully understanding COVID-19 impacts. However, methodologies for capturing these issues and processes can be complex and require nuance. For instance, without careful attention to survey item construction, survey questions may promote xenophobic attitudes, even when the investigator's purpose is to study and dissuade such attitudes. Investigators are reminded to be sensitive to these issues when designing their research. The IRB has developed a brief Best Practices document to assist investigators. See the Cultural Sensitivities and Surveys link on the [IRB-HSBS Guidance](#) website for more information.

SELECTED RESEARCH METHODS TOPICS

(Note: this is NOT a comprehensive list, nor does it represent all fields/disciplines. It includes an initial set of topics offered by research colleagues with example resources. Additional suggestions are welcome, and we expect to continue more systematic engagement with our U-M research community around human subjects research and fieldwork needs as the COVID-19 conditions and associated research impacts evolve.)

Quick Transitions to Remote/Social Distancing Methods: Best Practices and Protocols

How can researchers quickly implement remote approaches - such as individual and group videoconferencing - with research participants and maintain research integrity and continuity?

Marhefka, S., Lockhart, E., & Turner, D. (2020). [Achieve research continuity during social distancing by rapidly implementing individual and group videoconferencing with participants: Key considerations, best practices, and protocols](#). *AIDS and Behavior*, 1–7. Advance online publication.

How can researchers effectively transition their in-person data collection to the online environment?

Braun, V., Clarke, V., & Gray, D. (Eds.). (2017). [Collecting Qualitative Data](#): A practical guide to textual, media and virtual techniques. Cambridge University Press.

Geisen, E. (2020). [Social distancing in market research: Pivoting in-person methodologies](#)
- (covers sampling, recruitment, response quality, replicating complex samples and designs, and qualitative research online)

Jowett, A. (2020). [Carrying out qualitative research under lockdown – Practical and ethical considerations](#)

Lupton, D. (editor) (2020). Doing fieldwork in a pandemic (crowd-sourced document). Available at: <https://docs.google.com/document/d/1clGjGABB2h2qbduTgfqribHmog9B6P0NvMgVuiHZCl8/edit?ts=5e88ae0a#>

Online Survey Methods

U-M Survey Resources:

Programming Support:

- [Qualtrics](#) (available to all U-M community members) has help and tutorial links to help users craft online surveys that support their research goals.
 - o [XM Basecamp: Learn Qualtrics with On-demand Training](#)
- [REDCap](#) is a secure, HIPAA-compliant, web-based application offering a streamlined process for rapidly developing databases in support of data capture for research projects. It is best suited for low to moderate complexity studies.
 - MICHR offers two online REDCap courses to support clinical research teams:
 - REDCap Basics: available [here](#).
 - REDCap Survey Basics: available [here](#).

Survey Methods:

- There are many good texts/articles on survey research methods. Research teams might consider educational offerings from *U-M's Survey Research Center* (one of the best in the world!) in the *Institute for Social Research*, including its [Summer Institute](#) programming, which will be offered remotely.
- See also the [IRB-HSBS Guidance](#) website for more information about the survey design consulting services offered by the Survey Research Organization of the *Institute for Social Research* at no cost to faculty, staff, or students.
 - o [Note: is moving your face-to-face research to survey approaches, as part of its review of exempt projects, the IRB may ask to review and revise your consent information or online survey instrument to address these concerns].
- See also the *Cultural Sensitivities and Surveys* link on the [IRB-HSBS Guidance](#) website for more information around best practices and avoiding pitfalls related to issues of diversity, equity, and inclusion.

Online Focus Group Methods*Example references and resource links:*

Researchdesignreview.com. (2020). [Focus Groups: Moving to the Online Face-to-face Mode](#).

Daniels, N., Gillen, P., Casson, K., & Wilson, I. (2019). STEER: Factors to consider when designing online focus groups using audiovisual technology in health research. *International Journal of Qualitative Methods*, 18, *International Journal of Qualitative Methods*, 14 November 2019, Vol.18.

Flynn, R., Albrecht, L., & Scott, S. (2018). Two approaches to focus group data collection for qualitative health research: Maximizing resources and data quality. *International Journal of Qualitative Methods*, 17(1), *International Journal of Qualitative Methods*, 13 January 2018, Vol.17(1).

Kite, J., & Phongsavan, P. (2017). Insights for conducting real-time focus groups online using a web conferencing service. *F1000Research*, 6, 122.

Krueger, R. A., & Casey, M. A. (2015). *Focus groups: A practical guide for applied research* (5th ed.). Thousand Oaks, CA: SAGE Publications, Inc.

Online/Virtual Interview Methods*Example references and resource links (for synchronous and asynchronous interview approaches):*

Salmons, J. (2012). *Cases in online interview research*. Thousand Oaks, CA: SAGE Publications, Inc. doi: 10.4135/9781506335155; [Text publisher site](#) and [Example chapter](#)

Barratt, M. J., & Maddox, A. (2016). Active engagement with stigmatised communities through digital ethnography. *Qualitative Research*, 16(6), 701–719. <https://doi.org/10.1177/1468794116648766>

Bampton, R., Cowton, C., & Downs, Y. (2013). The e-interview in qualitative research. In *Advancing research methods with new technologies* (pp. 329-343): IGI Global.

Burns, E. (2010). Developing email interview practices in qualitative research. *Sociological Research Online*, 15(4), 24–35. <https://doi.org/10.5153/sro.2232>

Janghorban, R., Latifnejad Roudsari, R., & Taghipour, A. (2014). Skype interviewing: the new generation of online synchronous interview in qualitative research. *International Journal Of Qualitative Studies On Health And Well-Being*, 9, 24152. <https://doi-org.ezproxy-b.deakin.edu.au/10.3402/qhw.v9.24152>

Diary/Journaling Methods

Example references and resource links:

Ahlin, Tanja, and Fangfang Li (2019). From Field Sites to Field Events: Creating the field with information and communication technologies (ICTs). *Medicine, Anthropology and Theory* 6(2): 1-24.

doi.org/10.17157/mat.6.2.6n55

<http://www.medanthrotheory.org/read/11334/from-field-sites-to-field-events>

Crozier, S. E., & Cassell, C. M. (2016). Methodological considerations in the use of audio diaries in work psychology: Adding to the qualitative toolkit. *Journal of Occupational and Organizational Psychology*, 89(2), 396-419.

Kaur, H., Saukko, P., & Lumsden, K. (2018). Rhythms of moving in and between digital media: a study on video diaries of young people with physical disabilities. *Mobilities*, 13(3), 397-410.

Use of Participant Cameras or other Participant First Person-Perspective Technology

Considerations, e.g.:

- *In photovoice or other similar participatory methods*
 - o Photovoice may be used as both a research method or as a journalistic tool for telling a story
 - o Key concern - privacy of individual being photographed; written permission (media release rather than informed consent) typically required to take and share a photo of an individual

In observational studies

- o Privacy concerns - is the observation taking place in a public or private space?

Example references and resource links:

Pink, S. (2015) 'Going forward through the world: thinking about first-person perspective digital ethnography between theoretical scholarship and applied practice' *Integrative Psychological and Behavioral Science*. 49(2): 239-252

Social Media Methods (Using Online Discussion Platforms)

Consideration: Researchers must be aware of the terms of use of various social media platforms, whether research is permitted and what data the platform may be collecting or sharing.

- *Creating social media platforms/groups for research and researching social media platform*
 - o Differences between public and private spaces (requiring registration)
 - Data from public resources typically exempt or not regulated by the IRB
 - Private spaces require informed consent or waiver of consent by the IRB
- *Use of data from public online discussion platforms*
 - o Twitter
 - o Reddit

Example references and resource links:

Stewart, B. (2017). "Twitter as method: Using twitter as a tool to conduct research." In *SAGE Handbook of Social Media Research*, edited by Luke Sloan and Anabel Quan-Haase, 251– 265. London: Sage.

Sampson, T., Ellis, D., and Maddison, S. (eds.) (2016). *Affect and Social Media*, London: Rowman and Littlefield.

Chen, J., & Neo, P. (2019). Texting the waters: An assessment of focus groups conducted via the WhatsApp smartphone messaging application. *Methodological Innovations*, 12(3), 2059799119884276. Available at: <https://journals.sagepub.com/doi/full/10.1177/2059799119884276>

Lupton, D., & Turner, B. (2018). 'I can't get past the fact that it is printed': consumer attitudes to 3D printed food. *Food, Culture & Society*, 21(3), 402-418.

Reisner, S.L., Randazzo, R.K., White Hughto, J.M., Peitzmeier, S., DuBois, L.Z., Pardee, D.J., Marrow, E., McLean, S., & Potter, J. (2018). "[Sensitive health topics with underserved patient populations: Methodological considerations for online focus group discussions.](#)" *Qualitative health research* 28(10): 1658-1673.

App Based Methods

Consideration: Researchers must be aware of the terms of use, data being collected by the company providing the app (confidentiality of subject data)

Example references and resource links:

Boase, J., & Humphreys, L. (2018). Mobile methods: Explorations, innovations, and reflections. *Mobile Media & Communication*, 6(2), 153-162. <https://doi.org/10.1177/2050157918764215>

Kaufmann, K., & Peil, C. (2019). The mobile instant messaging interview (MIMI): Using WhatsApp to enhance self-reporting and explore media usage in situ. *Mobile Media & Communication*, Online first, 1-18. <https://doi.org/10.1177/2050157919852392>

Kaye, L.K., Monk, R.L., & Hamlin, I. (2018). 'Feeling appy?' Using app-based methodology to explore contextual effects on real-time cognitions, affect and behaviours. In C. Costa & J. Condie (eds.), *Doing research in and on the digital. Research methods across fields of inquiry* (p. 11-30). Abingdon, UK and New York: Routledge.

Sugie, N. F. (2018) 'Utilizing smartphones to study disadvantaged and hard-to-reach groups', *Sociological Methods & Research*, 47(3), pp. 458–491. doi: 10.1177/0049124115626176.

Contact Information: To share further thoughts/ideas, questions, and resources, please feel free to contact our tool-kit team via the feedback form below:

- *UMOR Tool-kit Feedback Form:*
https://docs.google.com/forms/d/e/1FAIpQLSfLp9iwqUS51-y8clE3tlm4lChDRwqREkKSFVd2V42_f5-dtA/viewform?usp=sf_link

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Resources also drawn from materials curated and compiled by:

- American Psychological Association (<https://www.apa.org/>)
- Jowett, A. (2020). [Carrying out qualitative research under lockdown – Practical and ethical considerations](#)
- [LSE Digital Ethnography Collective Reading List](#) (crowd-sourced bibliography)
- Lupton, D. (editor) (2020) Doing fieldwork in a pandemic (crowd-sourced document). Available at:
<https://docs.google.com/document/d/1clGjGABB2h2qbduTgfqribHmog9B6P0NvMgVuiHZCl8/edit?ts=5e88ae0a#>