HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

March 2021

In This Issue

Contact Us

Human Research Protection Program

Blount Hall, Room 408
1534 White Ave.
Knoxville, TN 37996-1529
865-974-7697
utkirb@utk.edu
irb.utk.edu

Office Hours
M-F: 8 a.m.– 5 p.m.

Announcements

Virtual Office Hours

HRPP office staff are currently working a hybrid schedule, with some days in the office and some days working remotely. If you need assistance, you can visit us during virtual office hours, visit us in person in the office (Blount Hall Rooms 408 and 410), or contact us by email and phone. Below is our office hours schedule:

Mondays from 2:00 – 4:00 pm — Ashley Brown (Zoom link here)

Tuesdays from 11 a.m. – 1 p.m. — Jenny Dunn (Zoom link here)

Wednesdays from 2:30 – 4:30 p.m. — Jennifer Engle (Zoom link here)

Thursdays from 9:00 – 11:00 a.m. — Rob Withrow (Zoom link here)

If these times do not work for you, we are happy to schedule an individual meeting. Please email your College Liaison to schedule a time to meet.

Guidance on Internet Research

The internet is a valuable resource for researchers and can be used both to identify and recruit potential study participants, as well as to collect research data. However, using the internet for research presents unique challenges in terms of privacy, confidentiality, and informed consent that sometimes require additional care to ensure that the rights and welfare of research participants are protected. Protection of human subjects is no less important when the research involves observation of online behavior.

What is human subjects research? An activity is considered human subjects research subject to IRB review if it involves collecting or using "identifiable private information" from individuals.

Definitions for Human Subjects Research Conducted Online:

Identifiable in this case means that an individual's identity is known or can readily be ascertained. For example, even if an individual's name is not published as part of a research study, publishing their username, or publishing direct quotes from them may mean that their identity can be readily ascertained.

Private information means "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes

by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)" [45 CFR 46.102(f)].

Data mining or data scraping means using information on the internet that is readily available to the public for research. For example, this might include analyzing public Twitter feeds or Facebook posts, information from public chat rooms, or public comments on news articles.

Intervention means any manipulation of the subject or subject's environment that is performed for research purposes.

Interaction means any type of communication or interpersonal contact between the investigator and the research subject.

What about collecting publicly available information online for research? Data mining or data scraping may not be considered human subjects research if:

- No intervention or interaction with individuals occurs; AND
- The data is presented in a de-identified manner or results are presented in the aggregate.

What about publicly available information that is sensitive? Some sensitive or personal information shared online may be publicly available but publishing it could cause embarrassment and/or reputational harm. For example, if an individual shares publicly online that they are a recreational drug user. Whenever possible, the HRPP suggests obtaining informed consent from these individuals before publishing this type of information in an identifiable manner.

What about private online information? The distinction between public and private information is sometimes difficult to make on the internet. Individuals may not pay close attention to privacy settings when they share information on social media, or they may not be aware of who can access the information they share. When conducting research that involves collecting data from social media sites, you must pay close attention to whether the individual user has placed restrictions on the use of their data (e.g., their profile is set to private). If you are using a personal social media account, you may be able to see information from individuals based on your online connections (e.g., friends of friends) that is not truly publicly available.

What if my project is human subjects research? If your project is human subjects research, the IRB must determine how the identifiable data being collected is being kept secure. If the data being collected includes direct or indirect identifiers, the IRB must determine whether disclosure of the private information outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. If the answer to this question is yes, then the researcher must take additional steps to ensure participant confidentiality is maintained.

What should be included in the informed consent? When applicable, participants should be informed of specific potential security risks related to online research. For example, by including a statement such as: "Although we will take steps to protect the confidentiality of your data, we cannot guarantee the confidentiality of information shared online."

Do I have to collect written informed consent? In some instances, the IRB can grant a waiver of the requirement to obtain written informed consent. A waiver can be granted when one of the criteria below is met:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality AND each subject will be asked whether the subject wants documentation linking the subject to the research; OR
- The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside the research context; OR
- Participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

What about using the internet to recruit participants? If you will be posting recruitment messages on personal social media accounts, the HRPP suggests turning off commenting for those posts to protect participant privacy, especially if your study involves a sensitive topic.

Posting recruitment messages online also means that you as a researcher may lose control over who sees and/or shares your recruitment message. This may result in fraudulent activity related to your study, such as bots (not real participants) completing your survey, or individuals who are not eligible for your study attempting to participate in it. If you are recruiting participants online, the HRPP suggests including procedures to verify participant identity and eligibility prior to participation.

If you will be posting recruitment announcements in online groups or on listservs, the HRPP recommends obtaining the appropriate permissions from group administrators before posting.

Pearls from PRIM&R

Alterations and Waivers of Informed Consent

Lora Beebe, your IRB chair here with some important information about alterations and waivers of informed consent. Source documents include DHHS regulations 45 CFR 46 subparts (c) and (f) as well as UTK HRPP policy and procedures. As a reminder we discussed the required elements of informed consent in the October 2021 newsletter. In brief, the required elements of informed consent are:

- statement that the study involves research
- explanation of the purpose(s) of the research
- duration of participation
- description of study procedures
- identification of any procedures that are experimental
- description of foreseeable risks
- description of benefits if any
- disclosure of alternate procedures if any
- description of measures to protect confidentiality
- if the study is greater than minimal risk, a statement about whether compensation is available for participants who might be injured as a result of study procedures
- contact information for whom to contact with questions, and
- statement that participation is voluntary

As PI, you can request to either:

- waive obtaining informed consent
- omit or alter one or more of the required elements of informed consent listed above
- waive the documentation of informed consent

Examples of studies in which a waiver of obtaining informed consent might be applicable are retrospective chart reviews, studies of existing pathology specimens and ethnographic research.

Studies using deception commonly obtain a waiver of one or more of the required elements of consent, since participants are not provided with an explanation of the true purpose of the study, which is a required element of consent.

A waiver of documentation is often requested for minimal risk online surveys, in which participants click a button at the beginning of the survey to agree to participate rather than physically signing a consent form.

Let's discuss these options in detail.

Under the revised Common Rule (applies to all research initiated at UTK since January 2019), you must satisfy **ALL** of the stipulations below to waive obtaining informed consent, or to omit or alter required elements of informed consent.

- The research or clinical investigation involves no more than minimal risk to participants;
- The research could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of participants; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may waive the requirement to obtain documentation of informed consent if **ANY** of the following criteria are met:

- The only record linking the subject and the research would be the informed consent form and the principal risk is breach of confidentiality (for instance, domestic violence research where the primary risk is discovery by the abuser). Each subject will be asked whether they want documentation linking them with the research, and their wishes must govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Examples include procedures like non-sensitive surveys, questionnaires and interviews.
- If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting informed consent.

Investigators take note! The informed consent process involves much more than simply having participants sign the consent form! Unless the IRB has granted a waiver of the requirement to obtain informed consent, investigators

who seek and receive approval for a waiver of documentation of consent still must conduct an appropriate consent process.

In cases in which the documentation requirement is waived, the IRB still requires the investigator to provide in the application materials a written summary of the information to be communicated to the subject, and the IRB will consider whether to require the investigator to provide subjects with a written statement regarding the research.

The IRB acknowledges everyone's efforts to conduct and document the informed consent process in accord with the highest ethical standards. On behalf of our participants, we are grateful for your attention to this critical part of the research process.

If you have study-specific questions or concerns, feel free to reach out any time to utkirb@utk.edu and/or (865) 974-7697.

Happy researching!
Lora Humphrey Beebe, PhD, PMHNP-BC, FAAN
UT IRB Chair

Research Match

The University of Tennessee, Knoxville has joined Research Match as a participating institution. Research Match is a free and secure online tool for connecting researchers with volunteer study participants.

The program facilitates the successful completion of human subjects research, which can often be delayed or not completed due to difficulties recruiting study participants. Any researcher who is conducting any type of health-related research can use Research Match to recruit participants. Researchers can also sign up for feasibility access before recruiting on Research Match to determine how many participants in their target demographic are volunteers on the site.

If you are interested, you can sign up to be a volunteer study participant as well.

If you have questions about using Research Match, please contact UT's institutional liaisons for the program:

- Jennifer Engle, Director, Human Research Protection Program (jengle@utk.edu or 974-7494)
- Ashley Brown, Assistant Compliance Officer, Human Research Protection Program (abrow269@utk.edu or 974-7687)

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		January	February
New Studies	Exempt	8.2	9.9
	Expedited	13.3	9.5

Amendments	Exempt	4.5	4.0
	Expedited	6.9	4.4

IRB Submissions:

Submission Type	Submissions	
	January	February
Pre-Review Changes	51	45
New Studies	67	74
Amendments	60	63
Change in Personnel	23	28
Continuing Reviews	48	30
Reportable New Information	8	2
Study Closure	8	7
Miscellaneous	0	1
TOTAL	**118**	**250**

Contact Us

General Questions (submission procedures, application and materials development, iMedRIS, etc.) contact us at (865) 974-7697 or utkirb@utk.edu.

Submissions that are currently in review, contact your unit's ***liaison***.

Reportable New Information (unanticipated problems, adverse events, complaints, concerns about participant welfare or safety, etc.), contact Lora Beebe (lbeebe1@utk.edu) or Jennifer Engle (jengle@utk.edu)

Reliance Agreements/Single IRB and Other Collaborative Research, contact Jennifer Engle (865-974-7494, jengle@utk.edu).

Education and Training, contact Jennifer Dunn (jdunn36@utk.edu).

ClinicalTrials.gov, contact Jennifer Engle (865-974-7494, jengle@utk.edu).

Human Research Protections Program
Office of Research & Engagement
Blount Hall, Room 408
1534 White Avenue
Knoxville, TN 7697
Phone: 865-974-7697
Fax: 865-974-7400
Email: utkirb@utk.edu
Website: irb.utk.edu