Subject: Researcher's Digest Volume 8
Date: Wednesday, September 30, 2020 at 11:37:03 AM Eastern Daylight Time
From: Banchik, Rebecca
To: Banchik, Rebecca

The Researcher's Digest

September 2020, Volume 8

Human subjects research can be tricky. It can be confusing. But The GC HRPP is here to help. The Researcher's Digest is a monthly newsletter that provides a space to share important updates, reflection on policies, spotlights on investigators and research, and some good fun.

COVID-19 Updates

[cuny.us4.list-manage.com]

[cuny.us4.list-manage.com]

[cuny.us4.list-manage.com]

How We Define Identifiable:

Identifiable means that the investigator can **readily ascertain or associate** the information with the individuals' identities. Examples of identifiers include names, social security numbers, medical record numbers, **OR** any code that permits the data to be linked to individually identifiable living individuals.

Considerations for Remote Research Activities

1. How will you maintain confidentiality of the data you collect?

-Where will your data be stored?
-Who will have access to the data?
-Will you record the study visits? Audio? Video?
-How is the data set saved? Coded? Anonymously? With direct identifiers?

2. What is your consenting process?

-Will you obtain signed, documented consent? How?
-Are you scheduling a phone or Zoom meeting to go over the consent?
-Are you requesting a waiver of documentation of consent in lieu of obtaining signature?

3. How will you recruit participants?

-Do you need approval to post recruitment materials on websites or social media platforms?
-What is the script you will use to contact eligible participants?
-Do you need to screen prior to obtaining consent?

3. Do you have the resources to conduct study procedures remotely?

-Do your participants have the correct computers, phones, apps, and

programs needed?
-Are there any documents, materials, tools, or measures that need to be mailed to participants?
-If you're providing compensation, will this be done electronically?

Please note that the GC is working on a plan for in-person human subjects research resumption. Once the process is approved, information will be made available on the HRPP website and through email communication. Until that time, non-therapeutic, non-beneficial research studies are to continue remotely and not in-person.

Below are some common attachments that you may include in your applications.

Attachment Types	Requirements
HSR CITI completion certificates	All research personnel including faculty advisors
Consent Forms	Template forms that may include documented consent, oral-internet consent, research information sheet (for exempt research), parental permission consent forms, child assent forms
Recruitment Materials	Any communications to prospective participants including advertisements, email introductions, social media posts, phone scripts

Exempt vs Expedited Review

Both exemptions and expedited approvals require IRB review for a determination.

An official decision from the IRB must be made before you may initiate any research activities including data collection and analysis.

Only not human subjects research (NHSR) studies may be conducted without prior IRB review since the activities do not meet the definition of human research and therefore the regulations do not apply.

Training & Office Hours

Rebecca Banchik offers virtual trainings and overviews of HRPP/IRB via video chat and screen sharing. Please contact her at rbanchik@gc.cuny.edu to set up a session.

If you would like a recorded training session on conducting research remotely, please email Rebecca and she can share the video for your viewing.

Zoom office hours are available. Outlook invites will be sent when a time has been set up.

Graduate Center HRPP [cuny.us4.list-manage.com]

CUNY Central HRPP [cuny.us4.list-manage.com]

IDEATE

Reminder: Any amendment to a project must be submitted through Ideate and approved prior to implementation.

Technical Issues? Email ideate@cuny.edu and include screenshots when appropriate. **Include:** PI name, submission type, title, protocol number, and description of issue.

Please Know: The COVID-19 pandemic has no impact on your submission or the IRB review process. All submissions are still received and reviewed through Ideate.

Consent Forms: Readability and Understanding

Readability

- Ask a friend or family member unfamiliar with your research to read your consent form. A well written consent should be understandable to anyone. Find out if the reader has questions or finds anything to be unclear or if there are details that are lacking in the document.
- Avoid complex terminology that only you as a specialist in your field would understand.
- Do not overburden your reader with literature review, background, or planned data analysis.

Risk Assessment

- Always include the potential risks associated with participation in the research.
- Although minimal, consider risks like feelings of fatigue, stress, or boredom from longer periods of participation.
- Because all studies involve some element of data collection, there always exists the risk of the potential loss of confidentiality of the data. This must be stated.

Template Requirements

- Children under 18 cannot consent for themselves, they may provide assent.
- Children are enrolled via parental permission consent forms.
- Translations of consent forms are required if you will enroll non-English speaking participants.
- If you will obtain oral consent, there should be no signature block on the consent form.

Procedure Requirements

- Make it clear to participants what is expected of them from beginning to end of enrollment.
- If any procedures are optional, state that and explain.
- It must be clear what, if anything, is to be audio or video recorded and why.
- Include how long procedures and study visits will take. Consider total time involved as well to provide a full picture of enrollment.
- State clearly what activities are to be conducted remotely.

Process, Not Just a Form

- Remember that consent is a process, not just a document.
- Time must be allotted to go over the consent with the eligible participants.
- Consent forms cannot be signed and returned without an opportunity for questions or clarifications.

How long does the HRPP take to conduct a review?

Expect a pre-review from the HRPP within 5 business days from submission.

Once project is ready for official review, reviewers have 5 business days to make a determination of approval or send comments.

Do you Zoom?

Zoom security is a top priority for CUNY.

Zoom Security Protocols [cuny.us4.list-manage.com]
and recommendations [cuny.us4.list-manage.com] required for those using a license to Zoom for any CUNY related activities.

Information Technology
it@gc.cuny.edu
it.cuny.edu [cuny.us4.list-manage.com]

Contact Information

Phone: (212) 817-7525
Email: rbanchik@gc.cuny.edu
Office: 3300.28

manage.com].