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
Human Subject: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Enrolling non-English speaking participants?

1. All participant facing materials must be translated and submitted for review and approval by the IRB. This includes recruitment documents, consent forms, and surveys/questionnaires, instructions.

2. Include a letter of attestation signed by the translator attesting to the accuracy and completeness of the translation. Indicate what
documents are translated and for what project.

3. If you are excluding other languages, in exclusion criteria you must justify why the study is only available to English speaking individuals.

### Distinguishing Differences Between Project Types Often Misinterpreted to All Be HSR

<table>
<thead>
<tr>
<th>Type</th>
<th>Intent</th>
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<tbody>
<tr>
<td>Human Subjects Research (HSR)</td>
<td>Conducting a systematic investigation, including research development,</td>
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<td>testing and evaluation, designed to develop or contribute to</td>
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<td>generalizable knowledge involving human subjects.</td>
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<tr>
<td>Quality Improvement (QI)</td>
<td>Intent of project is to improve a practice or process within a</td>
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<td></td>
<td>particular institution or ensure it conforms to expected norms.</td>
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<tr>
<td>Program Evaluation (PE)</td>
<td>Intent of project is to evaluate a specific program, only to</td>
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<td></td>
<td>provide information for and about that program.</td>
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### Considerations for Remote Research Activities

**Reminder:** All HSR CITI certificates must be uploaded to the Attachments tab (label as CV) for PI, advisor, and any other research personnel listed in the application.

**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:** If you are recruiting verbally on the phone or in-person, you must provide the IRB with a script that will be used to recruit participants. Upload all recruitment material to the Recruitment sub-tab and Attachments tab as instructed.

### HSR Project Review Categories

**Not Human Subjects Research**
Minimal risk research determined not to involve human subjects:
Determination made, approval not required

**Exempt**
Project Outline and expectations

- Divide project into phases if you plan to conduct remote activities now, but in-person in the future.
- Outline procedures and consider how they will be done without in-person engagement.

Data security plans

- Consider level of risk and how to manage these risks relating to confidentiality.
- Understand the security and data storage procedures on the remote platform you’re using.
- Consider privacy from participants’ location – how do you ensure consent and active enrollment are done safely? Privately? Without someone falsifying responses?

Vulnerable populations

- Consider how you will obtain assent remotely from children.
- Know your population and what their environment will be during a remote home visit or interaction.

Timeline/Resources/Cost

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.

Minimal risk projects that are exempt from the regulations and administratively reviewed. In order to qualify for review, the research must fall into at least one of the exempt categories as defined by the federal regulations.

- Expedited
  - Minimal risk research projects that fall under at least one of the expedited categories: approval granted, annual review no longer required.

- Full Board
  - Greater than minimal risk projects: Approval granted for one year, annual review required.

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?
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.

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Zoom security is a top priority for CUNY.

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

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