

THE GEORGE
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WASHINGTON, DC

Tips for an Easier Review

Ensuring IRB Submissions are
Complete

GW IRB Days
September 15-17, 2015



OHR Office Steps

Triage

- Study is submitted to OHR
- CITI training & document signatures checked
- If cleared study is passed on to IRB analyst

IRB Analyst review

- Make sure every question is answered and every document is submitted & PI has no expired/administratively closed studies
- Look for missing information in application/consent (use checklist)- make sure study is ready to be approved (exempt submissions) or approved by IRB designee (expedited submissions) If missing information analyst sends out pre-review
- Exempt studies are approved by analyst & approval sent out. Expedited studies go on to...

IRB designee review

- The designee completes a more scientific review as well as ensuring the study meets all federal regulations
- IRB designee signs off on study and gives back to analyst who then sends out approval OR gives analyst stipulations sent out to PI & contact- approval sent out once stipulations are met

General Top 10

1. Plan ahead!
2. Be sure ALL research team members have current CITI and/or HIPS as needed
3. Obtain all necessary signatures from appropriate bodies
4. Provide all necessary supplements & documents
5. Don't short cut on the forms! Proof read and make sure to go over your documents a second time
6. Clearly explain any acronyms or study specific language in the IRB application form responses- write the application as if someone outside your specific field will be reading it.

IRB FORMS:

<https://humanresearch.gwu.edu/IRBforms>

7. If you are analyzing de-identified data that has been purchased or obtained from an organization, such as NIH, please mention whether or not you will be signing a Data Use Agreement.
8. If you are conducting research anywhere other than GW, remember to submit a site permission letter from that site, OR, if they have their own IRB, explain whether the other IRB has already reviewed/approved the research. Common locations include schools, clinics, and rehabilitation centers.
9. Use our website for consent writing to make sure your consents will meet every necessary element. Tips:
 - ❖ When using multiple consent forms, clearly label which consent form is for which population and which activity in the document title, not just in the file name. Example: "Phase 1- Consent Form - Adults - Interview" and "Phase 2-Consent Form - Adults - Focus Groups."
 - ❖ For expedited research studies involving consent, ensure that you are including all required elements of consent. For example, stating that "records will be kept confidential" is not sufficient; you must describe how you are maintaining secure records, such as with encrypted hard drives or locked cabinets.
 - ❖ If your subjects include children of a wide age range (ages 7-17), make sure to submit two assent forms: one for the younger children (7-12), one for older children (13-17).
10. If you are planning a study with multiple stages, be sure both stages can be adequately reviewed in detail. If the second stage depends on the results of the first, you can wait and submit the second stage as a modification.

CONSENT WRITING TOOLS:

<https://humanresearch.gwu.edu/research-tools>

Initial Review

- **Identifiers.** When drafting your application, think carefully about whether you want identifiers versus whether you need identifiers.
- **Responding.** When the analyst sends you an Preliminary Review, it's helpful to respond directly to that email.

Modifications

- If your modification is something that affects study documents, the changes should be easy to find and specifically outlined in the modification form.
 - ❑ *Modification summary example:* We have updated the inclusion criteria, changed Sponsors, and shortened the duration of the interview from 60 to 30 minutes. Changes are found:
 - ❑ Consent form: page 1, paragraph 1; page 2, paragraph 3
 - ❑ IRB Application: sections 5.1 and 6.4
 - ❑ Funding Source Supplement HRP- 220, page 1

Modifications

- If your modification involves a change in compensation, consider how that will affect subjects who have already been compensated.

Continuing Reviews

- **Multi-phase studies.** If your study has multiple aims or phases, clearly indicate in both the updated IRB Application and the continuing review form which phase you are currently in.

Continuing Reviews

- **Enrollment numbers.** Remember what the IRB considers to be “enrolled” subjects. If you have people that screened out, never started study procedures or never signed a consent form, they should not be included in the enrollment total.

Continuing Reviews

- **Accompanying documents.** Be sure to send an up-to-date protocol/application and consent form along with the renewal form if your study is still open to enrollment.

Continuing Reviews

- **Proofing.** Do a quick proof read to make sure every necessary question on the form is answered - even if you just need to check off “N/A.” If you have made any modifications in the past year, even staff changes, make sure to select “yes.”

Closures

- Ensure your final enrollment numbers make sense compared to the numbers you listed at your most recent continuing review.
- If you want to store identifiable data, make sure to explain the reasons why. If the data is for future research, provide an estimate as to when you would seek IRB approval again.

Questions?

Our website:

<https://humanresearch.gwu.edu>