CCAS Research with Human Subjects Town Hall
Time: Dec 15, 2020 12:00 PM Eastern Time

Sheila Garrity - AVP for Research Integrity
Rebecca Eberle - Interim Director of the Office of Human Research

Rebecca shared her slides on what OHR has done for the IRB process since COVID-19 has affected research at the university. Slides can be found on the CCAS Research blog.

How is IRB working?
Researchers have been able to continue to do research with animals during the pandemic.

GW is making efforts to keep human subjects and researchers safe during the pandemic with the use of guidance documents and prioritizing certain research over others.

The IRB office staffing is reduced to the point where only one person has CIP certification, some people are ready to sit for the certification testing soon. We lost two IRB analysts during summer 2020, and are trying to get back to the capacity we had before the pandemic hit.

Process, how it works, what slows things down
There has been an increase in IRB submissions due to COVID-19 research, both new submissions and modifications.
> How to make modifications to existing studies: https://humanresearch.gwu.edu/changes-approved-studies

OHR is experiencing an increase in rush review requests because of COVID-19 related research. OHR has a higher workload and a shorter staff. As a result, OHR Implemented a rush request form - available on the OHR website - and made some changes to the rush request process to better meet the needs of PIs during this unusual time.
> Rush Requests https://humanresearch.gwu.edu/rush-review-request
> COVID-19 Related Guidance https://humanresearch.gwu.edu/covid-19

What's OHR doing well
IRB meeting attendance has increased and IRB meetings are more efficient.
New rush review processes have allowed for COVID-19 related research to have faster review times.
New COVID-19 questions in IRB Application help facilitate review for Social Behavioral and Biomedical research happening in-person so that OHR isnt sending back questions for PIs to change their study.

OHR is currently prioritizing the review of submissions due to:
- funding deadlines;
- graduation requirements/deadlines; and
- COVID-19 related studies.

DIfferent types of IRB Review
There are strict rules about what kinds of research may receive which review. IRB analysts determine whether a study is exempt or expedited based on the risk to the subjects in the study. Minimal Risk studies- including Exempt review and Expedited review. Full Board is for studies that may have greater than minimal risk. Types of Review: https://humanresearch.gwu.edu/reviewtypes

IRB Review Process
Exempt:
Triage- submission queue done by Lacey and checks iRIS for signatures and CITI training
IRB Analyst review- does a peer review and a collaborative process
IRB Exempt registration - research team will receive a IRB exempt memo indicating that it can be exempt

* Timing in getting exemption for student research, concerned about timing with graduation- OHR is staffing up soon and training so that analysts can conduct exempt review more quickly. OHR has worked with other schools to determine recommended deadlines for student research so that there isn't a last minute crunch right before graduation. OHR is happy to work with CCAS to establish these expectations as well.

Expedited:
Triage
IRB Analyst review
IRB Designee review- designee sees things that an IRB analyst may miss in the review, they are experts in the field of study and of the regulations, once stipulations are fixed by the researchers, the designee moves the study forward for IRB approval

Full Board:
Triage
IRB Administrator review - IRB Administrator conducts review of submission and assigns to a full board meeting for review
IRB full board review- Applications are assigned to a meeting when the board meets twice a month

What slows things down:
Stipulations- no CITI training, unsigned forms, incomplete applications, inconsistent info across documents, missing documents,
Tips: Before submitting an application, especially when there's a student involved in the research, PI should check the documents for consistency and complete documents before submitting.
If doing a survey, and it's not included in the application, make sure to include info when the survey will be administered and send modifications to OHR so that the application doesn't get sent back with stipulations.

New Guidance
Reopening research has three components:
- Mitigate Risk - see Appendix B under **Resuming Human Subjects Research** in COVID-19 guidance section on OHR Website- https://humanresearch.gwu.edu/covid-19
- Inform subjects of new risks (related to COVID 19 or otherwise)
- Departmental prioritization of research - Appendix A under **Resuming Human Subjects Research** in COVID-19 guidance section on OHR Website- This is to prevent overcrowding and overuse of resources in the university https://humanresearch.gwu.edu/covid-19

Department approval should be obtained for resubmitting and resuming research.

What to submit to IRB
Existing studies that already have IRB approval but have been on pause, should get departmental approval first to restart their work and in-person interaction. Submit PRIF form in iRIS that indicates the intent to resume research & certify use of the information form/addendum.
New studies need departmental approval to include in-person interactions. Include in the IRB application that the information sheet/addendum will be used.

New information sheet/consent addendum- posted on OHR website with consent templates, doesn't need IRB approval as long as no edits or changes to the document are made. Submit consent addendum for currently enrolling studies. For reopening studies where subjects already consented, provide the form and submit a modification to waive signature when reopening a study.

ohrirb@gwu.edu   humanresearch.gwu.edu
202-994-2715

Q: We need some guidance about how to deal with remote (via computer) consents and HIPAA releases.
A. 	GW is not a HIPPA covered entity, although does have a HIPPA advisor related to the hospital. OHR reviews the HIPAA waivers but is not the final sign-off. Electronic consent is now accepted, you can use something like DocuSign, Red Cap. Ask GWIT about verified signature programs.

Q:Also, NIH has finally agreed to our remote human subject testing - how can we speed receiving IRB modification approvals?
A. 	Waiver of document of consent can be requested. Rush request form- https://humanresearch.gwu.edu/rush-review-request can be sent to ohrirb@gwu.edu

Q: Restarting studies, if a portion of it isn't conducted at GW, can it resume or does it need to go through the department approval process?
A. 	Should go through the department first and be sure to check the box on the IRB form saying they received department approval.

Q: New information sheet needs to be filled out?
A. 	Can be found https://humanresearch.gwu.edu/research-tools

Q: Is it useful to have a checklist of common errors for the applicant to check through before submitting to make lighter work for the Triage staff? Possibly something that can go on the OHR website.
A. 	OVPR is working on trying to update the websites across sponsored research, OHR, etc. Rebecca is working on this.

There are office hours on Webex each Thurs 1-3pm for people to join Rebecca with their questions https://humanresearch.gwu.edu/contact-us. Reach out to the main OHR email ohrirb@gwu.edu with questions in advance so that Rebecca or an IRB analyst has some background before meeting with you during office hours.