GW OHR Guidance:

Submission Requirements

This guidance document establishes the requirements for submissions to the Office of Human Research. This document should be used by investigators and research team members who would like more information about the requirements for submission.

What documentation is required for an IRB application?

Applications submitted for IRB review must include sufficient information to allow the IRB to make the determinations required by DHHS and FDA regulations. Depending on the type of research and subject population, the documents required may differ. The iRIS system will help guide the submission process and includes a section requesting study documents. For every study, the IRB Application is required for submission.

Tip: If your study is greater than minimal risk, a written protocol is required. There are protocol and consent form templates on our website at https://humanresearch.gwu.edu/research-tools.

What signatures are required and why?

Submission forms must include electronic sign-offs from the following:

1. **Principal Investigator**
2. **Department Chair**
3. **MFA required signatures for all studies involving the MFA**

The signature process for studies ensures the study has undergone a review to make sure the study is appropriate, meets departmental standards, and all required protocol and regulatory information has been provided.

What training is required?

CITI training completed within the previous two years must be present for all research team members. There are several modules that may need to be completed depending on the nature of your research. We recommend taking the course that applies to your research as well as appropriate additional courses if your study is a clinical trial. Please see the charts on the next page for more information on the specific recommended courses.

Tip: Specific departments and/or sponsors may have their own training requirements. Please check with your department and study sponsor (if applicable) to see if additional training is required.

Research Classification

	Biomedical Research	Social/Behavioral Research	Both biomedical and social/behavioral	Clinical Trials
Recommended CITI Training Modules	Biomedical Investigators - Human Research	Social & Behavioral Research - Human Research	Both Biomedical and Social & Behavioral modules	Either the Biomedical or Social & Behavioral modules depending on the nature of the clinical trial
	Alternative: IRB Members- Human Research	Alternative: IRB Members- Human Research	Alternative: IRB Members- Human Research	Alternative: IRB Members- Human Research
	CITI Health Information Privacy and Security (HIPS) for Clinical Investigators		CITI Health Information Privacy and Security (HIPS) for Clinical Investigators	CITI Health Information Privacy and Security (HIPS) for Clinical Investigators
				GCP Training

What happens if my study is incomplete?

If your application does not include the proper signatures or documentation it will be returned to you during the triage process and will not be assigned to an IRB analyst until corrections are made. The Principal Investigator (PI) and primary contact will be notified when an application does not include the required material.

Where can I find templates for study documents?

Templates for consent forms, assent forms, protocols, and creation guides can be found on our website under "Research Tools." Using our templates is not required but is encouraged.

Questions?

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