06/25/2015

Dear GW Research Community,

The Office of Human Research (OHR) and the Institutional Review Board (IRB) are undergoing improvements! One new IRB Application has replaced the former Synopsis and Exempt Application. Supplemental forms to the new application have been developed for research that requires special considerations. The new forms will facilitate the collection of the information required by the regulations and the IRB, which will improve the IRB review process and in turn, allow OHR to better serve the GW research community. In addition, many new and updated policies are now available on the OHR website. Please always download forms from the website to ensure you are using the most recent versions and visit the research tools and Policies pages often.

Please see below for a detailed description of form updates and policy changes. We welcome your feedback on the changes.

We truly appreciate your patience and understanding as we continue to strive to enhance the protections for research participants, improve our service, and grow as a research institution.

Sincerely,

Office of Human Research

New and Updated Forms

IRB Application: The former Expedited/Full Board Synopsis form and Exempt submission form have been combined into one IRB Application form (HRP-200).

Please use this document for ALL new IRB submissions. If you believe your research will meet the criteria for exemption, you may choose to only complete the questions in orange. If it determined that the research does not meet the criteria for exemption, you will be asked to complete the remaining questions, rather than fill out a completely new form.

Problem Report Form: This has been updated to the Promptly Reportable New Information Form (HRP-572). This new form accompanies the new policy, “Prompt Reporting Requirements HRP-801”.

Consent Templates: Consent templates are now available for Biomedical research (HRP-500) and Social/BehavioralResearch (HRP-501). There is also a new consent statement template for exempt research (HRP-503).
**HIPAA Waiver Requests:** The forms for Full HIPAA Waiver Request (HRP-280) and Partial HIPAA Request (HRP-281) have been updated.

**IRB of Record:** When GW will be serving as the IRB of Record, please complete Form HRP-573. When another institution will be serving as the IRB of Record, please complete Form HRP-574. Please also review the revised procedures before submitting an IRB of Record request to OHR.

**Modification Form:** The Modification form (HRP-203) has been revised. Please use the revised form for all modifications to expedited and full board studies, as well as for exempt studies when the modification will change the risks to participants.

**Continuing Review Form:** The request for Continuing Review (HRP-202) has also been updated. Please use this document for all expedited and full board continuing review request. As a reminder, exempt research does not require annual review.

**Closure Form:** The Closure request form (HRP-206) has been revised. Please use this document for all expedited and full board closure requests. Studies that have been registered as exempt do not require closure with the IRB.

**Research Personnel changes:** Submit the Research Personnel Form (HRP-201) at initial and continuing reviews, or any time the study team changes. A modification is no longer needed if the only change being made is to the study team.

**IRB Application Supplemental Forms**

**Funding Source Supplement:** Submit the Funding Source Supplement (HRP-220) with the IRB Application form (HRP-200) for funded projects.

**Student Investigator Responsibilities Checklist:** Submit the Student Investigator Responsibilities (HRP-290) with the IRB Application form (HRP-200) for all student-initiated research including undergraduate, graduate, doctoral, law, and medical student research. One form for student group projects is sufficient, but all students should sign the document before submitting.

**Prisoner Certification Supplement:** Submit the Prisoner Certification Supplement (HRP-291) with the IRB Application form (HRP-200) when conducting research with prisoner populations. Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45CFR46.303 (c)).

**Children Supplement Checklist:** Submit the Children Supplement Checklist (HRP-292) with the IRB Application form (HRP-200) when conducting research with persons who have yet to reach age of majority.
*Assent Template* (HRP-506 and HRP-507): Assent templates for children ages 7-12 and 13-17 are available for use.

*International/Non-English Speakers Supplement:* Submit the International/Non-English Speakers Supplement (HRP-293) with the IRB Application form (HRP-200) when conducting international research or research with persons who cannot speak or understand English.

*Waiver or Alteration of Consent Supplement:* Submit the Waiver or Alteration of Consent Supplement (HRP-294) with the IRB Application form (HRP-200) when requesting a waiver of consent, waiver of documentation of consent, or an alteration of consent.