

Principal Investigator Exception Form (HRP-208)

Please review the Policy on Principal Investigators (HRP-011) for a description of who is permitted to act as PI of human research studies reviewed by the GWIRB. When completed, please submit this form to OHRIRB@gwu.edu with your IRB Application. Please also include a copy of the proposed Principal Investigator's CV, letter of appointment, and any additional supporting documentation.

Name of Proposed Principal Investigator: _____

Current Appointment/Title: _____

School (if applicable) and Department/Center/Institute: _____

Campus Address: _____

Campus Phone Number: _____

Email: _____

Study Title/IRB Number: _____

If you are seeking an umbrella PI exception for multiple studies, please provide a justification for the umbrella exception: _____

Sponsor: _____

Brief description of scope of work of the project: _____

Justification for request waiving PI eligibility requirements: _____

Assurances and Signatures

Proposed Principal Investigator:

- My signature indicates that I have reviewed this IRB Application form and supporting documents.
- I will complete and maintain human subjects protection training for the duration of this research project.
- I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as outlined in Federalwide Assurance of Protection for Human Subjects, for which GW is registered with OHRP/DHHS, and as detailed in GW HRPP Policies & Procedures. I will be guided by the principles contained in the Belmont Report and The Code of Federal Regulations governing research with human subjects (45CFR46 and 21CFR50).
- I have verified that all members of the research team have agreed to accept the responsibilities required of their roles and I provide my assurance that all will be kept fully briefed on the details of the study.

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<ul style="list-style-type: none">• I have queried all members of the research team to determine if they have a conflict of interest in this study as defined by GW policies.• I will follow all the additional PI requirements as detailed in “Policy: Principal Investigator’s Responsibilities (HRP-004)”.	
Proposed GW PI Signature: _____	Date: _____
<ul style="list-style-type: none">• The individual has the necessary experience and independence to conduct for his/her research project and to provide oversight to students as necessary.• The department, school, center, or institute is committed to supporting the proposed PI by providing appropriate space, resources and administrative oversight in the event that the waiver be granted.• The department, school, center, or institute will ensure that the proposed PI completes human subjects protection training before any engaging in any research determined to be human subjects. The approved HSP training site for GW is the Collaborative Institutional Training Initiative (CITI).• Should the proposed PI leave GW, the department, school, center or institute agrees to assume responsibility for the research project.	
Department Chair Signature (required): _____	Date: _____
Dean Signature (required): _____	Date: _____
<i>Additional Signatures Required for research that involves EITHER GW hospital and/or MFA data and/or patients OR if the PI is MFA faculty:</i>	
Dr. Mardi Gomberg-Maitland’s signature: _____	Date: _____
Dr. Robert Miller’s signature: _____	Date: _____

For Office of Human Research Use ONLY

<input type="checkbox"/> Proposed PI has current CITI <input type="checkbox"/> Proposed PI does not have any expired or administratively closed studies <input type="checkbox"/> Request Approved <input type="checkbox"/> Request Denied. Reason: _____	Date: _____
OHR Designee Signature	