# GW OHR Guidance:

**When GW is Relying on another IRB:**

**Consent Form Checklist**

This guidance document includes information about editing an existing consent form or writing a consent form for a study that has an external reviewing IRB (lead site) and GW is relying on this external reviewing IRB.

The reviewing (lead) IRB is responsible for considering local context, including state laws and institutional requirements. Local context typically requires changes to recruitment and consent documents so that participants have correct information.

OHR has created this checklist for the GW PI/team to use when creating the GW site-specific consent form. You will need to submit the GW site-specific consent form to OHR for our review when requesting a reliance in which GW is relying on another IRB. A redlined draft is acceptable for our review purposes.

Also consider whether these checklist items are applicable to assent forms, information sheets, and/or recruitment materials.

**GW Relying Consent Form Checklist**

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|  | **Identifying Information**: In addition to listing the Reviewing (Lead) IRB, add “George Washington University” and identify us as a “Site Institution.” You may also use “George Washington University Medical Faculty Associates” or “George Washington University Hospital”, as appropriate. |
|  | **Identifying Information**:In addition to listing the Lead IRB’s PI, add the name of the GW PI and identify this person as “Site PI”.  *Example template language:*  PI at George Washington University*: [Name]* |
|  | **Contact for Study Questions and Injury**: Provide the GW PI’s contact information  *Example template language:*  The person in charge of this study at the George Washington University is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {Principal Investigator, PI}. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: {PI contact information}. |
|  | **Disclosures**: Disclose financial or other conflicts of interests (COIs) on the part of any GW PI and/or GW study team member in the appropriate section and indicate if GW has reviewed the COI.  *Example template language:*  An individual [Name if appropriate] responsible for the conduct of this research study has a financial interest in *the study drug or the medical device being used in this research study.* *[Include information about the conflict of interest as appropriate]* |
|  | **HIPAA Authorization**: If Protected Health Information (PHI) will be accessed, used, created, or disclosed from GW, MFA and/or GW Hospital medical records, insert the following language:  *The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form*  *The use and release of protected health information is for the purpose of collecting data for this study.*  *Protected Health Information to be shared: [list all PHI that will be used or disclosed for this specific study]*  *Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:*  *Hospitals: <List by name>*  *Clinics: <List by name>*  *Other Providers: <List by name>*  *Health Plan: <List by name>* |
|  | **Injury**: Insert GW’s standard language when injury information is needed:  *The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.*  *[Include if compensation for research related injury is not available. Otherwise delete and insert language detailing compensation and medical treatment available.] If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.*  *You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.* |
|  | **Costs (GW, MFA, and/or GW Hospital)**:  Include any costs that may be incurred at GW, MFA, and/or GW Hospital due to the research. Indicate whether participants will be financially responsible for any clinic/hospital charges. |
|  | **Information about sites (GWU, MFA, and/or GW Hospital):**  Consider if your study is taking place at GW, MFA, and/or GW Hospital. Please include the relevant entity in appropriate sections. |