**The George Washington University**

**Institutional Language**

**GW Reliance on an External IRB**

The George Washington University (GW) institutional language must be added to any MODEL consent document provided by a sponsor or lead site when GW researchers are obtaining consent from research participants and GW is relying on an External IRB.

You must submit this completed checklist and *redlined* versions of consent documents to GW OHR for review *prior to* submission to the External IRB.

List all consent documents *by name* that require GW Institutional language: (e.g., consent form(s), assent form(s), information sheet(s) or educational material(s), recruitment material(s)):

Check each box in the left column. If you deviate from the language on this form, you must document the deviations and rationale in the last row.

**GW Institutional Language**

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| [ ]  | **Site Identifying Information**: In addition to listing the Reviewing (Lead) IRB, add “George Washington University” and identify us as a “Site/Institution.” If your study is taking place at “George Washington” (GW), “George Washington University Medical Faculty Associates (MFA)”, and/or “George Washington University Hospital” (GW University Hospital), include the relevant entity in appropriate sections. |
| [ ]  | **GW PI Identifying Information**:In addition to listing the Lead IRB’s PI, add the name of the GW PI and identify this person as “Site/GW PI”. |
| [ ]  OR[ ]  N/A | **Disclosures**: If the study is covered by a COI Management Plan, add the disclosure language included in the plan.  |
| [ ]  | **Contact for Study Questions and Injury**: Confirm the GW PI’s contact information is accurate and reflected throughout the GW consent, where appropriate |
| [ ]  | **Compensation and Treatment for Injury.** Include the MR or GTMR italicized language below verbatim:**SBS or Biomedical Minimal Risk (MR) Research** ***What happens if I believe I experience a problem or complication from this study?****Although risks are unlikely, it is possible that you could develop a problem or complication as a result of being in this research study. If you experience a problem or complication and treatment is required, seek treatment at any medical facility. The costs of treatment may be billed to you or your insurer just like any other medical costs. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be responsible for any costs. Funds to compensate you for pain, expenses, lost wages and other damages caused by the problem or complication are not available. This does not prevent you from trying to obtain compensation through the legal system.**Please contact the Principal Investigator listed in this consent form, as soon as possible, if you experience a problem or complication.***SBS or Biomedical Greater than Minimal Risk (GTMR) Research*****What happens if I believe I experience an injury or medical complication from this study?****If you experience an injury or medical complication and treatment is required, seek treatment immediately at any medical facility. The costs of treatment may be billed to you or your insurer just like any other medical costs, or covered by another third party, depending on a number of factors. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be responsible for any costs. Funds to compensate you for pain, expenses, lost wages and other damages caused by the injury or medical complication are not available. This does not prevent you from trying to obtain compensation through the legal system.**Please contact the Principal Investigator listed in this consent form as soon as possible, if you experience an injury or medical complication.*   |
| [ ]  OR[ ]  N/A Research is Not HIPAA-regulated | **HIPAA Authorization:** If Protected Health Information (PHI) will be accessed, used, created, or disclosed from a hospital or clinic that must comply with HIPAA, you must include the italicized language below verbatim. Delete the red/highlights before finalizing.***How will my privacy and health information be protected?****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, the provision of health care, or the payment of healthcare. This information is called “protected health information (PHI).”* *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 a more detailed description of how your protected 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 protected health information will only be used or shared as explained in this authorization form.**The information the study team will use and share includes:** *Information they collect or create to see if you qualify to take part in this study*
* *The results of the exams, tests, and other procedures you take part in while you are in this study*
* *Questionnaires or surveys you complete for this study; and*
* *The observations the researchers and study team members record during study visits and phone calls.*

*We will use and share your protected health information to collect data for this study.* ***Who may disclose my protected health information?*** *The researcher and the other members of the research team may obtain your individual health information from:*[note: Delete types of covered entities that do NOT apply to this study]*Hospitals: [List by Name]**Clinics: [List by Name]**Other Providers: [List by Name]**Health Plan:* [*List by Name]**And from hospitals, clinics, healthcare providers, and health plans that provide healthcare to you during the study* *By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study to:* * *The members of the research team*
* *Other healthcare providers such as labs, which are part of the study*
* *A safety monitoring board [include only if applicable]*
* *Regulatory authorities in the United States, such as the U.S. Food and Drug Administration, or in other countries. [Include only if the study is FDA regulated]*
* *Institutional officials at GW who are responsible for compliance*
* *The sponsor of this study or any agents or monitors of the sponsor, if applicable*
* [List additional entities that may receive PHI. Delete this line if not applicable]

*Once your health information has been disclosed or shared, the information may no longer be covered by the federal regulation that protects privacy of health information.**Some of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to conduct this study. The test results may be recorded in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care [will also] OR [will not] be included in your medical record.*[OR use this alternative statement:]*All tests are being done only because you are in this study. The study results will [will not] be [given to you to send] OR [sent] to your healthcare provider to include in your medical record.*Consider adding: *You have the right to access the information in your medical record. However, if you take part in this study, you agree to suspend this right until you are no longer in the study* *Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed to conduct this study.**This Authorization does not have an expiration date.**However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission. To cancel your permission, you will need to send a letter to [name Principal Investigator] stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:* ***[enter the name and address of the Principal Investigator].******Instructions****: for HIPAA-regulated research where an LAR will provide consent, ensure documentation on the signature page of the LAR’s authority to sign and provide consent on the participants behalf (e.g. parent, spouse, durable power of attorney).* |
| [ ]  OR[ ] none | There are deviations from the requests above. List deviations and rationale:       |

**GW PI Signature**

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| **GW PI Signature (required):** | Date: |