**IRB Authorization Agreement**

**Name of Institution or Organization Providing IRB Review (Institution A)**: George Mason University

**IRB Registration #**: IRB00001275

**Federalwide Assurance (FWA) #**: FWA00000549

**Name of Institution Relying on the Designated IRB (Institution B)**: Click or tap here to enter text.

**OHRP Federalwide Assurance (FWA) #**: Click or tap here to enter text.

The Officials signing below agree that Institution B may rely on the designated IRB for review and continuing oversight of its human subject research described below:

|  |
| --- |
| **Institution A** |
| Study Title | Click or tap here to enter text. |
| Institution A Principal Investigator | Click or tap here to enter text. |
| RAMP Study Number | Click or tap here to enter text. |
| Sponsor or Funding Agency | Click or tap here to enter text. |
| Award Number, if any | Click or tap here to enter text. |
| **Institution B** |
| Institution B Principal Investigator | Click or tap here to enter text. |
| External Study Number, if any | Click or tap here to enter text. |

**The Reviewing Institution’s IRB agrees to the following for the above-listed research protocol or activities:**

1. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.
2. Arrange for prompt reporting to the Relying Institution’s IRB of any of the following, as defined and determined by the Reviewing Institution’s IRB:
	1. Any unanticipated events or problems involving risks to subjects or others.
	2. Any serious or continuing non-compliance.
	3. Any suspension or termination of IRB approval.

**The Relying Institution remains responsible for the following:**

1. Ensure research activities at its site are in compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance.
2. Conduct any local ancillary reviews per institutional policy.
3. Conduct any reviews required by a HIPAA Privacy Board, including issuance of any waivers or alterations of HIPAA Authorization as appropriate
4. Adhere to its institutional conflict of interest (COI) policies and procedures, which includes providing the Reviewing Institution with any applicable COI management plan(s) related to the study.
5. Ensure principal investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including, but not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.
6. Maintain, implement, or have access to a human research post-approval monitoring (PAM) process, function, program, or service that is not directly involved with the research. The institution can conduct and report the results of for-cause and not-for-cause audits of the research study listed above to ensure compliance with human research protection regulations and other relevant requirements. The PAM process, function, program, or service should be able to monitor research under this Agreement and ensure any relevant findings are reported to the Reviewing Institution upon request.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such a time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official (Institution A):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Print Full Name: Christopher DiTeresi, PhD

Institutional Title: Associate Vice President, Research Integrity and Assurance

Signature of Signatory Official (Institution B):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Print Full Name: Click or tap here to enter text.

Institutional Title: Click or tap here to enter text.

Appendix A

Please provide the contact information for the individual at Institution A and Institution B who should be copied on all correspondence regarding the study.

Institution A: George Mason University

Name: Sarah K. Clark, MPH, CIP, CHRC

Institutional Title: Director, Human Research Protection Program

Email: sclark68@gmu.edu

Institution B: Click or tap here to enter text.

Name: Click or tap here to enter text.

Institutional Title: Click or tap here to enter text.

Email: Click or tap here to enter text.