

**sIRB Authorization Agreement**

**INSTRUCTIONS:** Investigators should complete the information in the box below and review the agreements following the box. Upon completion, the form should be sent to the IRB Contact for routing and signatures.

<b>Regis University Principal Investigator</b>	
<b>Regis University PI Email and Phone</b>	
<b>Regis University IRB Contact Name</b>	Alan Stark
<b>Regis University IRB Contact Email and Phone</b>	<a href="mailto:astark@regis.edu">astark@regis.edu</a> 303.458.4188
<b>Other Participating Institution Name</b>	
<b>Other Participating Investigator</b>	
<b>Other Participating IRB Contact Name</b>	
<b>Other Participating IRB Contact Email and Phone</b>	
<b>Other Participating OHRP Federal wide Assurance (FWA) #</b>	
<b>IRB Study Number</b>	
<b>IRB Protocol Title</b>	
<b>Will Regis students be involved as human subjects research participants in this protocol?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

**The Reviewing Institution’s IRB agrees to the following in regard to 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 any of the following, as defined and determined by the Reviewing Institution’s IRB:
  - a. Any unanticipated events or problems involving risks to subjects or others.
  - b. Any serious or continuing non-compliance.
  - c. Any suspension or termination of IRB approval.
3. Copy all appropriate IRB’s on correspondence to regulatory agencies if reporting of an event is required.
4. IRB meeting minutes will be made available upon request.
5. Comply with all applicable Federal, State, and Local laws and regulations.

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

1. Ensuring research activities at its site are in compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance.
2. Adhering to its institutional conflict of interest policies and procedures and providing the Relying Institution with any applicable COI management plan related to the study.
3. Ensuring 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 is not limited to, having the required professional staff appointments, credentialing,

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IRB@Regis.edu

- insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.
4. Maintaining, implementing or have access to a human subjects research post approval monitoring (PAM) process, function, program or service not directly involved with the research that 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 subject’s protections regulations and other relevant requirements. The PAM process, function, program or service must monitor the conduct of research under this Agreement and ensure any relevant findings are reported to the Reviewing Institution.

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 time that either institution provides 30 days written notice of termination to the other institution.

\_\_\_\_\_ Date: \_\_\_\_\_  
Regis University IRB Chair/IRB Vice-Chair

\_\_\_\_\_ Date: \_\_\_\_\_  
Other Institution’s Institutional Official/IRB Chair Signature

\_\_\_\_\_ Date: \_\_\_\_\_  
Other Institution’s Institutional Official/IRB Chair Printed Name

Appendix A

IRB Registration #: IRB00005686  
Federal wide Assurance (FWA) #, if any: FWA00010784  
[IRB@Regis.edu](mailto:IRB@Regis.edu)