INSTITUTIONAL REVIEW BOARD MEMORANDUM OF UNDERSTANDING
BETWEEN
GEORGIA REGENTS UNIVERSITY
AND
UNIVERSITY OF GEORGIA

Georgia Regents University (GRU) and University of Georgia (UGA) maintain separate, active Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP) under the U.S. Department of Health and Human Services. Both institutions use OHRP’s current policy guidance on defining when an institution is considered to be engaged in research covered by the Common Rule and each institution’s assurance.

Where both institutions are considered engaged in the conduct of human subjects research, this Memorandum of Understanding (“MOU”) sets forth the express agreement between GRU and UGA to facilitate the Institutional Review Board ("IRB") review of research studies using a streamlined IRB process that avoids duplication of review.

The parties signing below therefore agree as follows:

1. GRU-UGA collaborative research studies shall be reviewed using an IRB process where only one institution, GRU or UGA, will serve as the reviewing IRB (“Reviewing IRB”) for both institutions through a deferral mechanism ("Deferral"). The other institution that defers review is designated as the deferring institution ("Deferring Institution").

2. The determination of which institution will provide IRB review is described in Appendix A. This MOU assumes that the Reviewing IRB shall have the required reviewer expertise. If it does not, the IRB with the required reviewer expertise will serve as the Reviewing IRB. Each institution reserves the right to conduct its own IRB review of any specific study, regardless of this MOU, as long as the other institution is notified of this determination in a timely manner. In cases where there is a question regarding which institution should be the Reviewing IRB, a determination will be made jointly by the Directors of GRU’s Office of Human Research Protection and UGA’s Human Subjects Office.

3. In a Deferral, the review and continuing oversight performed by the Reviewing IRB will meet the human subjects’ protection requirements of the Deferring Institution’s OHRP-approved FWA.

4. Both GRU and UGA shall abide by the applicable federal, state and institutional requirements for the protections of human subjects research. Each Institution
remains responsible for ensuring compliance with its own IRB’s determinations and with the Terms of its OHRP-approved FWA. The Reviewing IRB will follow written procedures for reporting its findings and actions to appropriate officials at the Deferring Institution. Relevant minutes of IRB meetings will be made available to the Deferring Institution upon request. Reviewing IRB will promptly and immediately forward to Deferring Institution any information regarding safety, adverse events, audits, or other protocol-relevant information. Deferring Institution will provide to Reviewing IRB any relevant communications between itself and the granting agency (if funded) and/or regulatory agencies.

5. The Principal Investigator is responsible for submitting the following documents to the Deferring Institution: IRB’s notification of initial approval of the study; the approved protocol; the current approved consent documents; continuing reviews and amendments; continuing review/amendment approvals; and, any decisions made by the Reviewing IRB regarding the study.

6. If it is determined by either party that this deferral mechanism is no longer effective and must be ended, both parties agree that this MOU will be terminated in a manner that will avoid harm or risk to the research subjects.

7. The undersigned Officials at Georgia Regents University and University of Georgia have read and agreed to all the terms above. This MOU is effective on the date executed by both parties below and shall remain valid until properly revoked or superseded.

AGREED TO:

On behalf of GRU:  

[Signature] Date: 5/24/14  
Mark W. Hamrick, Ph.D.  
Senior Vice President for Research

[Signature] Date: 5/8/14  
Anthony L. Mulloy, Ph.D., D.O.  
Senior Associate Vice President for Clinical Research Administration

On behalf of UGA:  

[Signature] Date: 6/10/14  
David C. Lee, Ph.D.  
Vice President for Research
## GRU-UGA IRB Review Deferral Guide

<table>
<thead>
<tr>
<th>Principal Investigator's Primary Appointment</th>
<th>Research Site(s)</th>
<th>Reviewing IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRU/UGA Faculty</td>
<td>GRU and/or Augusta Community</td>
<td>GRU</td>
</tr>
<tr>
<td>GRU/UGA Faculty</td>
<td>UGA and/or Athens Community</td>
<td>UGA</td>
</tr>
<tr>
<td>GRU/UGA Faculty</td>
<td>GRU and UGA</td>
<td>Determined by the location of PI’s academic office</td>
</tr>
<tr>
<td>GRU/UGA Faculty</td>
<td>Non-Affiliated</td>
<td>Determined by the location of PI’s academic office</td>
</tr>
<tr>
<td>UGA</td>
<td>GRU</td>
<td>GRU</td>
</tr>
<tr>
<td>GRU</td>
<td>UGA</td>
<td>UGA</td>
</tr>
<tr>
<td>UGA</td>
<td>GRU and UGA</td>
<td>UGA</td>
</tr>
<tr>
<td>GRU</td>
<td>GRU and UGA</td>
<td>GRU</td>
</tr>
<tr>
<td>GRU</td>
<td>Non-Affiliated</td>
<td>GRU</td>
</tr>
<tr>
<td>UGA</td>
<td>Non-Affiliated</td>
<td>UGA</td>
</tr>
</tbody>
</table>

**GRU/UGA Faculty.** These are faculty/researchers with both GRU and UGA appointments.

**Non-affiliated site.** A location other than GRU, UGA, and its communities; this may include, but not limited to, local, statewide, national, or international locations. If applicable, a separate IRB Authorization Agreement (or Individual Investigator Agreement) will be established with the non-affiliated site (or individual investigator) if site (or investigator) is determined to be engaged in the conduct of human subjects research.

**PI.** Principal Investigator