This Agreement is entered into by and between the Medical University of South Carolina (MUSC), The University of South Carolina (USC), The Greenville Hospital System (GHS), Palmetto Health (PH), Clemson University (CU), and Spartanburg Regional Healthcare System (SRHS). These institutions shall be collectively referred to in this document as the “Collaborating Institutions”.

I. BACKGROUND

A. The Collaborating Institutions engage in biomedical, behavioral, and educational research, including research involving human subjects. This research is performed with the purpose of contributing to the growth of knowledge and the improvement of the health and welfare of individuals and mankind. The Collaborating Institutions are committed to safeguarding the rights and welfare of human subjects involved in research activities conducted under the direct and indirect sponsorship of their respective institutions.

B. Accordingly, each of the Collaborating Institutions has an Institutional Review Board (IRB) which reviews research involving human subjects. In addition, each of the Collaborating Institutions has executed a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP). The FWAs, approved by OHRP, provide that each institution will conduct research in compliance with established ethical principles and applicable regulations of the United States Department of Health and Human Services (DHHS) set forth in Title 45 of the Code of Federal Regulations Part 46, as amended. The FWAs provide an established, OHRP-approved framework for conducting a broad range of research activities.

Some of the research conducted by the Collaborating Institutions consists of industry-sponsored clinical trials of drugs and devices, which are subject to regulation by the Food and Drug Administration (FDA). Such research must be reviewed and approved by an IRB under the provisions of Title 21 of the Code of Federal Regulations Parts 50 and 56, as amended.

C. Each Collaborating Institution, through its OHRP-approved FWA, has designated reliance upon each of the other institutions’ IRB(s). This reliance allows the institutions to cooperate in human research studies while avoiding duplication of effort with respect to IRB reviews.

D. The Collaborating Institutions wish to enter into this Agreement to facilitate the research conducted at their institutions by streamlining the IRB process when two or more of the Collaborating Institutions are involved in the same research project.

II. SCOPE OF THIS AGREEMENT

A. This Agreement concerns review of human research studies involving two or more of the Collaborating Institutions. The Collaborating Institutions agree that, subject to the terms and conditions of this Agreement, a Study may be reviewed by a single IRB at any of the Collaborating Institutions. The Collaborating Institutions further agree that, as provided in this Agreement, such a review may be relied upon by any of the Collaborating Institutions. Regardless of this Agreement, each of the Collaborating Institutions reserves the right to its own IRB review.

B. Choice of IRB - The Collaborating Institutions will use the following guidelines for determining which IRB should review a Study:

1. When a Study anticipates that human subjects participating in the research are or will be enrolled exclusively at one of the Collaborating Institutions, the IRB of that institution will review the Study for all interested Collaborating Institutions.

2. When a Study involves human subjects at more than one of the Collaborating Institutions, the IRB Administrators shall confer (in consultation with the IRB Chairs) and have the authority to determine
which IRB shall be designated to review the Study. The decision shall be in writing and will be based on consideration of the following factors:

- where the preponderance of subject enrollment is to occur;
- where the preponderance of clinical research interactions (if any) with the subjects will occur;
- where the principal investigator is an employee or staff affiliate, including connection to a sponsored research project (e.g. grant funded project), and;
- which IRB has the requisite expertise to review the study.

3. When one of the Collaborating Institutions' IRBs has been designated to review a Study, the other involved Collaborating Institutions shall have the opportunity to participate, through their respective IRB Chairs, or designees, in the designated IRB's review process. This is intended to foster familiarity with institutional constraints, populations across institutions, and other factors important to the approval and conduct of said Study.

C. A review performed by a designated IRB will meet the human subject protection requirements of each Collaborating Institution's OHRP-approved FWA. The designated IRB will follow agreed upon procedures for reporting its findings and actions to the appropriate officials at the Collaborating Institutions. Relevant minutes of IRB meetings and pertinent file documents shall be made available to a Collaborating Institution upon request. A Collaborating Institution may not administratively overrule disapprovals of a designated IRB. Additional specific operating procedures may be developed, as needed, by the IRB Administrators, in cooperation with appropriate institutional officials.

The officials signing below agree that the reviews, approvals, and continuing oversight performed by their institutions' IRB(s) satisfy the requirements of the DHHS regulations for the protection of human subjects, and that each institution will be responsible for ensuring compliance with the designated IRB's determinations.

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Vice President for Research and Economic Development  
Clemson University  

John R. Raymond, MD  
VP for Academic Affairs and Provost  
Medical University of South Carolina  

Michael C. Riordan  
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