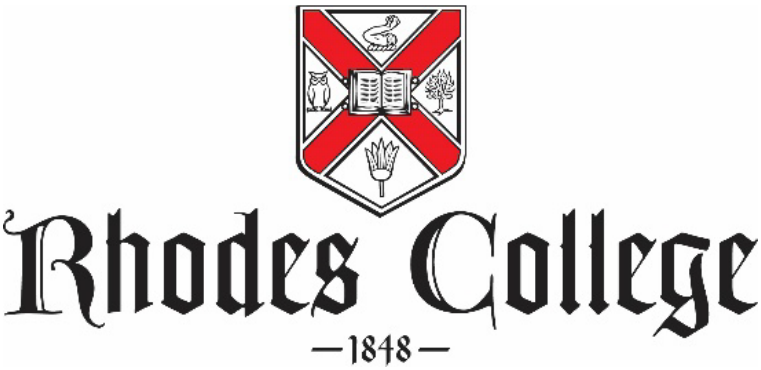

IRB AUTHORIZATION AGREEMENT

This Agreement is entered into by and between the institutions identified below.

Name of Institution Providing IRB Review ("Reviewing IRB"):

Name of Organization/Institution:	
Street Address:	
City:	
State:	
Zip Code:	

Name of individual responsible for administration of the IAA:	
Title of Individual:	
Phone Number:	
Email address:	

Name of Institution Relying on the Reviewing IRB ("Relying Institution/IRB"):

Name of Organization/Institution:	
Street Address:	
City:	
State:	
Zip Code:	

Name of individual responsible for administration of the IAA:	
Title of Individual:	
Phone Number:	
Email address:	

I. Scope of the Agreement:

1.1 The Officials signing below agree that the Relying Institution may cede IRB review and continuing oversight of its human subjects research to the Reviewing Institution/IRB as described:

☐ The agreement is limited to the following specific protocol(s):

Name of Research Project:	
IRB Study # at Reviewing IRB:	
Principal Investigator at Reviewing Institution/IRB:	

IRB Study # at Relying Institution:	
Principal Investigator at Relying Institution:	

☐ The agreement applies to research that meets the following criteria:

II. Responsibilities of Reviewing IRB

2.1 Perform initial and continuing reviews of submitted research, reviews of amendments; reviews of unanticipated problems that may involve risks to subjects or others; reviews of noncompliance that may represent serious or continuing noncompliance; reviews of local context information provided by Relying Institution/IRB; and reviews of other documents, as needed to be consistent with the applicable federal regulations.

2.2 Maintain and make accessible to the Relying Institution/IRB the IRB application, protocol reviews, letters to the investigators, approvals, disapprovals, and the minutes from the IRB meetings relevant to the protocol.

2.3 Notify the Relying Institution/IRB immediately in the event of a suspension or termination approval of all or part of the research that is not being conducted in accordance with the requirements of Reviewing IRB.

2.4 Ensure that an institutional mechanism exists by which complaints about the research can be made by local research participants or others to a contact at the Reviewing IRB.

2.5 Provide researchers at the Relying Institution/IRB the informed consent document to use for the research where the Reviewing Institution/IRB has determined that a consent form is required. The Reviewing Institution/IRB will permit a Relying Institution/IRB to customize limited site-specific sections of the consent form: use of institutional logo in header, authorization to use and disclose protected health information for research purposes (if relying institution acts as the privacy board), participant injury; local contacts, and signature lines. Any such modifications will be subject to approval by the Reviewing Institution/IRB, which will then provide a final approved consent document to the Relying Institution/IRB.

2.6 Report determinations of Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval to OHRP, FDA, or any other applicable agency, as required under applicable rules or regulations.

2.7 Upon request, provide the Relying Institution/IRB with a copy of the Reviewing Institution's Institutional Review Board (IRB) Standard Operating Procedures.

2.8 When appropriate, conduct on site or remote post-approval monitoring or directed audits.

III. Responsibilities of Relying Institution/IRB

3.1 Comply with the terms of this Agreement.

3.2 Ensure that the Principal Investigator(s) and other key study personnel at the Relying Institution/IRB are appropriately qualified and meet the Relying Institution's/IRB's standards for eligibility to conduct research.

3.3 Provide the Reviewing Institution/IRB with any local context information applicable to the research.

3.4 Provide the Reviewing IRB with the specific wording to complete the identified site-specific sections of the consent form as outlined in Section 2.5 above.

3.5 Notify the Reviewing IRB immediately if there is a suspension or restriction of the investigator(s) at the Relying Institution/IRB.

3.6 Ensure the safe and appropriate performance of the research at the Relying Institution/IRB. This includes but is not limited to: monitoring study compliance, reviewing major protocol violations, and any unanticipated problems involving risks to subjects and other that occur at the institution.

3.7 Require the Principal Investigator at the Relying Institution/IRB to maintain appropriate approvals, and other correspondence documenting the review and approval of the research as required by the regulations.

3.8 Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

3.9 Not approve research if it has not been approved by the Reviewing Institution/IRB; however, this does not preclude Relying Institution/IRB from conducting further review and approval or disapproval of research that has been approved by Reviewing Institution/IRB.

3.10 Cooperate with and provide reasonable assistance to the Reviewing Institution/IRB in conducting directed audits as applicable. Nothing in this Agreement shall preclude Relying Institution/IRB from conducting its own post-approval monitoring of the research.

IV. Both parties agree to the following provisions:

4.1 Review by other ancillary committees when required will be completed by the following institution:

4.1.1 Radiation Safety
- ☐ Reviewing Institution
- ☐ Relying Institution

4.1.2 Institutional Biosafety Committee (IBC)
- ☐ Reviewing Institution
- ☐ Relying Institution

4.1.3 Research Conflict of Interest
- ☐ Reviewing Institution
- ☐ Relying Institution

Determinations of ancillary committees at Relying Institution should be provided to the Reviewing Institution/IRB when pertinent to the review and determinations.

4.2 The Institution/IRB designated below shall serve as the privacy board for consideration of HIPAA authorizations and/or waiver requests for the use and disclosure of PHI.

- ☐ Reviewing Institution/IRB will serve as Privacy Board
- ☐ Relying Institution/IRB will serve as Privacy Board

4.3 This Agreement will become effective upon full execution by the parties and will remain in effect for as long as IRB review for the above referenced research is required or until the Agreement is terminated pursuant item 4.4 below.

4.4 The Agreement will be terminated in its entirety in the event that:

4.4.1 The Parties mutually agree to termination;
4.4.2 The Reviewing or the Relying Institution/IRB terminates its participation under this Agreement upon thirty (30) business days' prior written notice to the other party.
4.4.3 The Reviewing Institution terminates IRB approval for the research.

Upon termination under this Section 4.4, the Parties will work together to determine the effect of such termination on the research and will work together to ensure an orderly transition of the research to another IRB, as applicable.

4.5 This agreement must be kept on file by both parties.

Signature of Signatory Official at Reviewing IRB:

_____	_____
Signature	Date
_____	_____
Print Full Name	Institutional Title

Signature of Signatory Official at the Relying Institution/IRB:

_____	_____
Signature	Date
_____	_____
Print Full Name	Institutional Title