

Division of Responsibilities

1. Reviewing Institution/IRB agrees that for the research covered by this IRB Authorization Agreement (this "Agreement"), Reviewing Institution/IRB will:
 - 1.1. Provide 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, and reviews of other documents, requests, or information related to the research.

authorized representative as stipulated by the Reviewing Institution/IRB; and

- 2.7.6. Promptly notifying Reviewing Institution/IRB of new safety information that may represent Unanticipated Problems Involving Risk to Subjects or Others, or Serious or Continuing Noncompliance in accordance with Reviewing Institution's HRPP Standard Operating Procedures.
- 2.8. Assist and cooperate with Reviewing Institution/IRB in the preparation of any report to notify OHRP, FDA, or any other applicable agency of 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 related to research at the Relying Institution.
- 2.9. 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's (ac)8.8 (0.9 (i

- 3.2.1. The Parties mutually agree to termination;
- 3.2.2. Either party terminates its participation under this Agreement upon thirty (30) days' prior written notice to the other party.
- 3.2.3. The Reviewing Institution terminates IRB approval for the research.
- 3.2.4. The Reviewing or the Relying Institution's FWA is suspended, restricted, terminated, or expires; or
- 3.2.5. The Reviewing IRB fails to remain registered with OHRP.

Upon termination under this Section 3.2, the Parties will work together in good faith to

~~On 10/13/2021 at 10:06 AM, the following email was received from [REDACTED] (mailto: [REDACTED]):~~

Contact Information

IRB Contact at Reviewing Institution/IRB

Name:

Title:

Phone:

Email:

IRB Contact at Relying Institution

Name:

Title:

Phone:

Email: