**IRB AUTHORIZATION AGREEMENT**

**Reliance upon an External IRB**

This agreement allows The University of Colorado Boulder’s IRB (CU Boulder) to rely upon an external IRB of record at another FWA Institution.

**Name of Designated Institution Providing IRB Review:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

OHRP Federalwide Assurance (FWA) #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Local Contact person regarding study under review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of Institution Relying on the Reviewing IRB:** University of Colorado Boulder

OHRP Federalwide Assurance (FWA) #: 00003492

Single IRB Coordinator: Misty.White@Colorado.edu

The Officials signing below agree that CU Boulder may designate and rely on the Reviewing IRB for review and continuing oversight of its human subjects research described herein.

**This agreement is limited to the following specific protocol:**

Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor or Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
|  | **CU Boulder** | **REVIEWING Institution** |
| **PI Name** |  |  |
| **Protocol #** |  |  |

By signing this agreement, both institutions have agreed that the Reviewing IRB will serve as the IRB of record and are agreeing to uphold their individual responsibilities as listed on page 2 of this document. The Reviewing IRB will follow written procedures for reporting its findings and actions to appropriate officials at CU Boulder. Relevant minutes of IRB meetings will be made available upon request. CU Boulder remains responsible for ensuring compliance with the Reviewing IRB’s determinations and with the Terms of its OHRP- approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

**Signature of Signatory Official at REVIEWING Institution:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Print Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Signatory Official at CU Boulder:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Jon Reuter, DVM, MPVM, DACLAM;

Associate Vice Chancellor of Research Integrity & Compliance

**The responsibilities of the REVIEWING IRB are to:**

1) Maintain an FWA with OHRP and the registration of its IRBs with both OHRP, and if relevant, the FDA;

2) Maintain a Board membership that satisfies the requirements of 45 CFR 46, and if relevant 21 CRF 50 and 56, and provide special expertise as needed from Board members or consultants to adequately assess all aspects of the study;

3) Make available to the CU Boulder IRB upon request, the Reviewing IRB Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of submitted Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the Principal Investigator of the research study subject to this agreement;

5) Maintain and make accessible to the CU Boulder IRB, the Reviewing IRB application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and minutes of the Reviewing IRB meetings relevant to the protocol;

6) Notify the CU Boulder IRB immediately in the event of a suspension or restriction of the Reviewing IRB’s authorization to review studies; and

7) Notify the CU Boulder IRB of any Reviewing IRB policy decisions or regulatory matters that might affect the institution’s reliance on Reviewing IRB reviews or performance of the research at the local institution.

**The responsibilities of the CU Boulder IRB are to:**

1) Maintain a Federal Wide Assurance (FWA);

2) Maintain a human subjects protection program, as required by the DHHS OHRP;

3) Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46 and, if relevant, 21 CRF 50 and 56;

4) Notify the Reviewing IRB immediately if there is ever a suspension or restriction of the local IRB’s authorization to review studies;

5) Ensure that the investigators and other staff at CU Boulder who are conducting the research are appropriately qualified and meet the institution’s standards for eligibility to conduct research;

6) Notify the Reviewing IRB immediately if there is a suspension or restriction of a listed investigator at CU Boulder;

7) Ensure the safe and appropriate performance of the research at CU Boulder. This includes, but is not limited to: monitoring study compliance; reviewing major protocol violations, and any unanticipated problems involving risk to subjects and others; ensuring a mechanism exists by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas should be shared with the Reviewing IRB and the Principal Investigator at Reviewing Institution;

8) Require the Principal Investigator at CU Boulder to maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations; and

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