**Institutional Review Board (IRB) Authorization Agreement**

Name of Organization or Organization Providing IRB Review (hereafter “**BRANY IRB”**):

**Biomedical Research Alliance of New York LLC Organizational Review Board**

OHRP IRB Registration #: IRB00000080, IRB00010793

Name of Organization Relying on the Designated IRB (hereafter **Organization**):

Federalwide Assurance (FWA) #:

[ ]  Check here if Organization does not have a Federalwide Assurance


The officials having signed below commit their Organization to rely upon BRANY IRB for review and continuing oversight of its human subjects research described below (check one):

[ ]  This Agreement is limited to the following specific protocol(s):

Study Title:

Sponsor/Funder and Protocol #:

Lead Principal Investigator (if applicable):

Organization Principal Investigator (if applicable):

[ ]  This Agreement applies to all human subject research studies Organization elects to submit to BRANY IRB for review.

The review performed by BRANY IRB will meet the human subject protection requirements of FDA and OHRP, as applicable. IRB review shall occur with voting membership and/or consultant supplementation appropriate to any given activity. Changes in voting membership shall be reported to the Office for Human Research Protections (“OHRP”) as they occur.

Responsibilities of the parties are as follows:

By BRANY IRB:

* Following written procedures for reporting findings and actions to appropriate Organizational officials;
* Confirming the competency of the investigator(s)
* Acting as the Privacy Board under 45 CFR Part 164 for trials reviewed by the BRANY IRB and consulting with Organization’s privacy officer and others designated by the Organization as needed to address relevant matters;
* Maintaining all records of IRB proceedings as required by law;
* Maintaining IRB meeting minutes;
* Conducting continuing reviews of already approved protocols;
* Terminating or suspending studies for cause (if indicated) and informing Organization thereof;
* Informing Organization of any other suspected serious or continuing non-compliance with human subjects laws and regulations;
* Informing Organization of any communication with the FDA, OHRP or funding agency relating to any BRANY IRB approved study;
* Reporting conflicts of interest disclosed by the Principal Investigator and/or key personnel to the conflicts of interest committee at Organization, as well as others designated by the Organization.

By Organization:

* Updating its FWA (if applicable) to designate reliance on the BRANY IRB;
* Abiding by BRANY IRB decisions and facilitating compliance with BRANY IRB’s determinations, and with the terms of this IRB authorization agreement and FWA, as applicable;
* Reporting to BRANY IRB unanticipated problems involving risks to human subjects or others, and any serious or continuing noncompliance with regulations governing human subject research, BRANY IRB approval, or Organization’s policies and procedures. (Note: Organizations holding an FWA must also promptly report to OHRP, and FDA for research involving FDA regulated products, the aforementioned determinations.)
* Designating the following: privacy officer and COI liaison for consultations with BRANY IRB;
* Reviewing reported conflicts of interest and advising the BRANY IRB of outcomes, including conflict of interest management plans if needed;
* Informing the BRANY IRB if a Principal Investigator has his/her privileges revoked at Organization, or has been disciplined by Organization for conduct that relates to a study;
* Informing BRANY IRB of any communication with the FDA, OHRP or funding agency relating to BRANY IRB studies

This document shall be kept on file by both parties and provided to FDA and OHRP upon request.

Signature of Signatory Official (**BRANY IRB**):

|  |  |  |  |
| --- | --- | --- | --- |
| **Signature:** |  | **Date (mm/dd/yyyy)** |       |
|  |  |  |  |
| **Printed Name:** |       | **Title:** |       |

Signature of Signatory Official (**Organization**):

|  |  |  |  |
| --- | --- | --- | --- |
| **Signature:** |  | **Date (mm/dd/yyyy)** |       |
|  |  |  |  |
| **Printed Name:** |       | **Title:** |       |