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

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

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

OHRP IRB Registration #: IRB00000080

Name and address of Organization Relying on the Designated IRB (hereafter “**Organization”**):

If applicable, provide Organization’s Federalwide Assurance (FWA) #:

Has the Organization’s FWA been extended to non-federally funded research?

[ ]  Yes [ ]  No

The officials having signed below commit their Organization to rely upon BRANY IRB to 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 potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of BRANY IRB; and reviews of other documents, requests, or information related to the approval and continuing oversight of the research, as applicable. The review and oversight of the research by BRANY IRB will be performed in accordance with its policies and procedures, the human subjects protection requirements of the Organization’s FWA(s), if applicable, any applicable federal human subjects research regulations and ethical principles referenced therein and any other applicable federal human subjects research regulations or policies. BRANY IRB will consider any local requirements communicated by the Organization to BRANY IRB. 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:

* Maintaining current IRB registration with OHRP
* Maintaining IRB membership that satisfies the requirements of any applicable federal human subjects research regulations or policies
* Making BRANY IRB policies and procedures available to Organization
* Maintaining records of its membership, its review activities and determinations, and other records as required by applicable federal regulations and BRANY IRB policy. Such IRB records shall be made available to Organization upon reasonable request, including, to the extent not restricted under applicable law, portions of meeting minutes relevant to the research
* Confirming Principal Investigators hold necessary licenses and have appropriate qualifications and experience to conduct the proposed research
* If Organization is a HIPAA Covered Entity, upon request BRANY IRB will act as the Privacy Board and make determinations as required by and in compliance with 45 CFR Part 164 for trials reviewed by BRANY IRB. BRANY IRB will consult with Organization’s privacy officer/liaison, as needed, to address relevant HIPAA matters

|  |  |
| --- | --- |
| Select One |  |
|  | Organization elects to have BRANY IRB serve as the Privacy Board as stated above |
|  | BRANY IRB will not serve as the Privacy Board for Organization as stated above |
|  | N/A - Organization is not a HIPAA Covered Entity |

* Providing informed consent forms to use for the research where BRANY IRB has determined that such a consent form(s) is required.
* Reporting conflicts of interest disclosed by the Principal Investigator and/or key personnel to the designated conflicts of interest representative at Organization. BRANY IRB will ensure that any management plan is incorporated into its review as applicable, and that any disclosures to subjects required by the plan, and approved by BRANY IRB are included in the approved informed consent form(s)
* Promptly notifying Principal Investigator of its determinations or review decisions for new or continuing research (e.g., approval, disapproval, required modifications); ; and of lapses in IRB approval and any applicable corrective action plans.
* Promptly notifying Organization and Principal Investigator of applicable review decisions as well as of any findings and actions (including any suspension or termination of IRB approval of the research and required corrective actions), with respect to: (i) any unanticipated problems involving risks to human subjects or others, (ii) subject injuries related to research participation, or (iii) significant subject complaints (e.g., those that could affect the conduct of the research) that occurred at the Organization, and, for research where BRANY IRB is serving as the single IRB (sIRB) such events or actions that occurred at any participating institution if such events or actions relate to or may affect the conduct of the research or the safety, rights or welfare of human subjects participating in the research at the Organization.
* Promptly notifying Organization and Principal Investigator of any findings of serious and/or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of BRANY IRB, or of apparent serious and/or continuing noncompliance with such regulations or requirements, as well as any actions taken (including any suspension or termination of IRB approval of the research) and the steps BRANY IRB deems necessary for remediation of the noncompliance at the Organization. For research where BRANY IRB is serving as the single IRB, the lead Organization and overall PI will also be notified of any suspension or termination of IRB approval and any remediation actions pertaining to findings of serious and/or continuing noncompliance if such finding or actions relate to or may affect the conduct of the research or the safety, rights, or welfare of human subjects participating in the research at other participating sites.
* Should BRANY IRB conduct an audit or investigation of an allegation or matter relating to IRB review, the findings will be reported to Organization in a reasonable timeframe. BRANY IRB will also inform Organization and PI of any corrective actions required. Organization may also adopt its own more stringent corrective actions. BRANY IRB may also request that Organization conduct its own audit/investigation and report its findings back to BRANY IRB. BRANY IRB and Organization may also work jointly to conduct an audit/investigation.
* Notifying Organization in advance if BRANY IRB determines that under applicable regulations or under the terms of the Organization’s FWA (if applicable) a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of any unanticipated problems involving risks to human subjects or others, serious and/or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of BRANY IRB, and/or any suspensions or terminations of IRB approval. Unless otherwise agreed to by the parties, BRANY IRB will draft the report and will provide Organization the opportunity to review and comment on the draft report before BRANY IRB/ Organization sends the report to the external recipients. BRANY IRB is under no obligation to adopt Organization’s comments. Nothing in this agreement shall prevent Organization from making its own report in addition to any report prepared by BRANY IRB. BRANY IRB and Organization may also agree to make a joint report.
* Promptly notifying Organization of any communications received from the FDA, OHRP, and/or other regulatory agencies regarding the reports of unanticipated problems, suspension, or termination of IRB approval, serious and/or continuing noncompliance, or other regulatory compliance concerns.

Responsibilities of Organization:

* For studies under the purview of BRANY IRB, accept the decisions and requirements of BRANY IRB, and implement the protocol approved by BRANY IRB including obtaining informed consent as applicable. Organization may not initiate any research or change to the research without first receiving prior approval from BRANY IRB, except where necessary to eliminate apparent immediate hazards to subjects
* Require its research personnel to provide any information about conduct of the research required for continuing review
* Require its research personnel to maintain all research records, including informed consent documents and HIPAA authorizations, in accordance with applicable federal, state, and local regulations.
* Communicate to BRANY IRB the requirements of any applicable state or local laws, regulations, organizational policies, standards, or other local factors, including local ancillary reviews, relevant to the research (“Local Context ”) that would affect the conduct or approval of the research at the Organization.
* Provide BRANY IRB with Organization specific information that is required for the informed consent form(s), for review and approval by BRANY IRB, when written informed consent is required. Once the consent form is approved for use Organization will not, and will require that its research personnel not, make any change to the form without obtaining prior approval of that change from BRANY IRB.

|  |  |
| --- | --- |
|  | **Check here if applicable** |
| Organization’s informed consent form requirements are attached |  |

* Maintain policies regarding the disclosure and management of research personnel conflicts of interest related to research and to share those policies with BRANY IRB, as requested.
* Ensure that the provisions of any applicable grant or contract that address financial coverage for research-related injuries in connection with research funded in whole or in part by a non-federal entity (e.g., corporation, foundation) are consistent with the approved research protocol and consent form or that the approved research protocol and consent form, if more protective of human subjects, will control.
* Ensure that an organizational mechanism exists by which complaints about the research can be made by local research participants or others to a local contact
* Work with BRANY IRB to establish whether a separate HIPAA authorization form will be used for research or whether HIPAA authorization language will be incorporated into the consent form.
	+ If a separate HIPAA authorization form will be used Organization will ensure the accuracy of the information within the form, the compliance of the form with the HIPAA Privacy Rule, and, as stated in such sections, that the form permits PHI to be used by and disclosed to BRANY IRB
	+ If the HIPAA authorization language will be incorporated into the consent document, the Organization will work with BRANY IRB to provide, as requested, any language specific to the Organization
* If Organization is a HIPAA Covered Entity and has elected not to have BRANY serve as the Privacy Board above, Organization will act as the Privacy Board under 45 CFR Part 164;
* Promptly notifying BRANY IRB of any specific local requirements and restrictions on use and disclosure of PHI that could prevent the IRB from approving a request for waiver of HIPAA authorization
* Require Principal Investigator(s) to promptly notify BRANY IRB of any unanticipated problems that may involve risks to human subjects or others, or any subject injuries related to research participation, or any significant subject complaints that occurred at the Organization.
* Promptly notify BRANY IRB of any potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of BRANY IRB in connection with the research at the Organization, and of any suspension or restriction by the Organization or any third parties of any of its research personnel’s authority to conduct the research.
* Cooperate, and require its research personnel to cooperate, with any audit or investigation by BRANY IRB of any matter under this agreement. Such cooperation will include, but is not limited to, providing Research records and related information, meeting with representatives from BRANY IRB and helping to carry out corrective action(s), as applicable.
* Promptly provide any comments on any draft report to external parties that will be made by BRANY IRB
* Promptly notifying BRANY IRB of any communications received from the FDA, OHRP, and/or other regulatory agencies regarding studies for which BRANY IRB has oversight
* Designating the following Organization liaisons in the table below including: Human Research Protection Program (HRPP) Officer, Conflict of Interest (COI) liaison, and Privacy Officer, if BRANY IRB is serving as the Privacy Board
* Informing BRANY IRB of any communication with/from the FDA, OHRP or funding agency relating to BRANY IRB studies

Please provide contact information for the following:

|  |  |  |  |
| --- | --- | --- | --- |
| Title | Name | Email | Phone |
| HRPP Officer |  |  |  |
| Conflict of Interest Liaison |  |  |  |
| Privacy Officer |  |  |  |

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:** |       |