**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, IRB00010793

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

**Organization Name:**

**Organization Address:**

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:

* This Agreement applies to Virtual Pooled Registry-Cancer Linkage System (VPR-CLS) requests submitted 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:

1. Maintaining current IRB registration with OHRP
2. Maintaining IRB membership that satisfies the requirements of any applicable federal human subjects research regulations or policies
3. Making BRANY IRB policies and procedures available to Organization
4. 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
5. Confirming Principal Investigators hold necessary licenses and have appropriate qualifications and experience to conduct the proposed research
6. Providing informed consent forms to use for the research where BRANY IRB has determined that such a consent form(s) is required.
7. 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.
8. 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.
9. Promptly notifying Organization and Principal Investigator 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.
10. 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.
11. 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.
12. 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.
13. 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.

By Organization:

1. 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
2. Require its research personnel to provide any information about conduct of the research required for continuing review
3. Require its research personnel to maintain all research records in accordance with applicable federal, state, and local regulations.
4. 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
5. 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
6. 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.
7. 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.
8. 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.
9. 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.
10. Promptly provide any comments on any draft report to external parties that will be made by BRANY IRB
11. 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
12. Informing BRANY IRB of any communication with/from the FDA, OHRP or funding agency relating to BRANY IRB studies
13. Designating an Organization liaison for communication with BRANY IRB:

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| --- | --- | --- | --- |
| **Title** | **Name** | **Email** | **Phone** |
| **HRPP Liaison** |  |  |  |

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

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

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

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

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