Streamlining the IRB Process with BRANY IRB and Single IRB Review

NCI CIRB initiative for review of studies using the Virtual Pooled Registry Cancer Linkage System (VPR-CLS)

Presented 10/25/2021 by Laura Donohue, CIP,
Linda Reuter, MS, CIP, and Raffaella Hart, MS, CIP

Agenda

- About BRANY IRB
- Virtual Pooled Registry Cancer Linkage System (VPR-CLS) studies
- Benefits of BRANY Central IRB review of VPR-CLS studies
- Communication, reliance agreements, and local context
- How BRANY IRB review fits into the existing process
- Responsibilities of involved IRBs
- Questions

Our History

- Biomedical Research Alliance of New York, LLC
- Organized in 1998
  - Initiative of the New York Academy of Medicine
  - BRANY owners:
    - NYU School of Medicine
    - Montefiore Medical Center
    - Icahn School of Medicine at Mount Sinai
    - Northwell Health
- Provide IRB services to academic medical centers, community hospitals, independent research sites, sponsors, and government agencies in the United States
  - Approximately 1600 active research studies (35% expedited review)
  - Approximately 200 exempt per year
  - BRANY employs over 100 professionals with expertise in human subject protection, clinical research administration, research education & research compliance

BRANY IRB's Approach

- BRANY IRB provides a proven infrastructure that adheres to the highest standards to ensure regulatory compliance while offering customer support that exceeds expectations.
  - Dedicated Project Manager
  - IRB Reliance Agreements Coordination (including SMART IRB reliance agreements if applicable)
  - Efficiency & Flexibility
  - Connected IRB Model
  - Expert Committee & IRB Staff

BRANY IRB

Quality Assurance

BRANY IRB is committed to continuous quality improvement, which is demonstrated by our successful accreditation history.

April
2004
Partnership of Human Research Protections (NCQA+JACHO)

December
2006
AAHRPP re-accreditation (First IRB in New York)

December
2009
AAHRPP re-accreditation

December
2014
AAHRPP re-accreditation

December
2019
AAHRPP re-accreditation

About BRANY IRB

Project Management

- Laura Donohue, CIP, IRB Supervisor, with support from:
  - Linda Reuter, MS, CIP, Director, IRB
  - Raffaella Hart, MS, CIP, Senior VP, IRB

- Single point of contact

- Establish a plan for IRB review that aligns with existing submission process for VPR-CLS requests

- Will work closely with requestors to ensure IRB submission and reviews go smoothly and any questions are addressed promptly

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BRANY IRB Leadership

Laura Donohue
IRB Supervisor

- Project manager for BRANY IRB review of registry data requests and studies using the Virtual Pooled Registry Cancer Linkage System
- Certified IRB Professional (CIP)
- More than 20 years of experience in research administration
  - 15 years as a clinical research coordinator
  - 6 years in IRB administration
- Responsible for:
  - Supervising BRANY IRB staff
  - Implementation of Standard Operating Procedures
  - Managing IRB review of ongoing research
- Assists with development and implementation of strategic goals for the BRANY IRB team

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BRANY IRB Leadership

Linda Reuter
Director, IRB

- Certified IRB Professional (CIP)
- More than 28 years of experience in IRB administration
- Responsible for:
  - Managing the IRB team
  - Compliance with IRB Standard Operating Procedures and applicable regulations
  - Managing IRB activities
  - Development of short- and long-term strategic goals
- Training and supervision of the IRB staff and committee members

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BRANY IRB Leadership

Raffaella Hart, MS, CIP
Sr. Vice President, IRB,
IBC and QA Services

- Certified IRB Professional (CIP)
- More than 20 years of experience in IRB administration
- Strategic planning and overall operations of the BRANY IRB
- Training and supervision of the members of the IRB team supporting this project.
- Negotiating IRB reliance agreements
- Gathering local research context details
- Establishing communication pathways

Virtual Pooled Registry Cancer Linkage System (VPR-CLS) studies

- Registry linkages for :
  - Cancer epidemiology cohort studies
  - Clinical trials
  - Post-marketing surveillance of a drug/device
  - Public health surveillance initiatives

- Linkage with cancer registries
  - Offers researchers complete, high quality, detailed, and standardized cancer information
  - Registry data being released was collected for a purpose other than the proposed research
    - Commonly considered secondary research
    - Release of data alone generally does not engage the registry in the research

- National linkages may be ideal for some studies

Why is BRANY Central IRB review for VPR-CLS studies needed?

- Multi-state registry linkage studies currently undergo multiple reviews by each involved registry and its IRB
  - Each registry and IRB has a different application process
  - Requesting linkages with multiple registries can take significant time
  - Each registry and IRB dedicates time to reviewing the same study
  - Timing of reviews is variable

Benefits of BRANY Central IRB review for VPR-CLS studies

- BRANY IRB review will eliminate need for separate (and multiple) reviews by each involved registry and its IRB
  - BRANY IRB will seek reliance agreement with each registry and/or its local IRB
  - A single reliance agreement will cover all VPR-CLS linkage studies
- Decrease administrative burden of duplicative registry/IRB review
- Ensure a consistent review process
- Minimize local/state request for protocol changes that necessitate re-review by institutional IRB
- Speed up timeline for review and release of data

Benefits of BRANY Central IRB review for VPR-CLS studies

- Compliance with Revised Common Rule's requirement for single IRB review for cooperative research

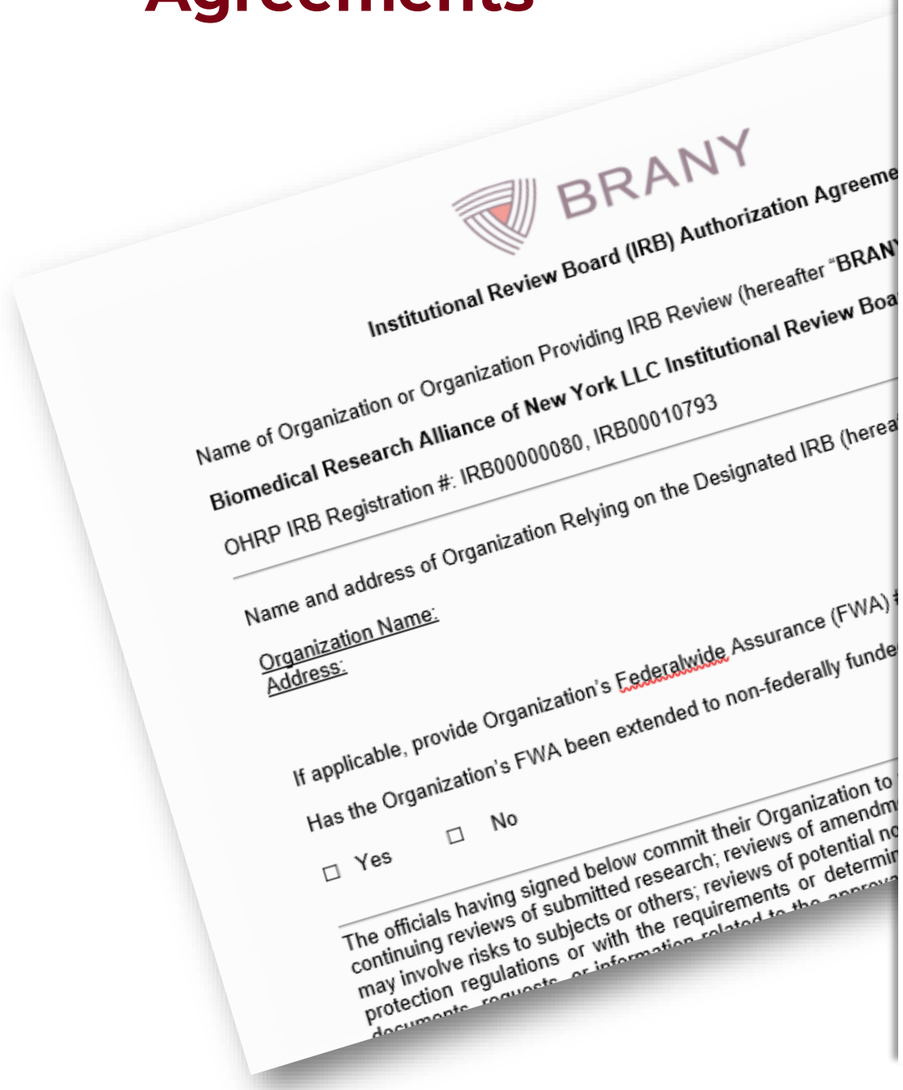
- Reduced administrative burden
  - No additional submission required
  - BRANY IRB will use the **TIRA**

- What is the TIRA?
  - **T**emplated **I**RB/**R**egistry **A**pplication
  - Single application
  - Adopted by 34/43 registries participating in the VPR
  - Researchers complete it once
  - Submitted to all involved registries and to BRANY IRB

Communication with Local Registries and Their IRBs

- Establish the IRB Authorization Agreement
- Understand local context
    - Requirements to allow release of data from the local registry
    - Determine which registry activities require IRB approval
    - What kinds of communication about ceded IRB review does the registry and/or IRB require?
        - Notification that BRANY IRB has received a submission involving the registry
        - Outcome of BRANY IRB review regarding submission involving the registry

More About Reliance Agreements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Institutional Review Board (IRB) Authorization Agreeme

Name of Organization or Organization Providing IRB Review (hereafter "BRANY

Biomedical Research Alliance of New York LLC Institutional Review Boa

OHRP IRB Registration #: IRB00000080, IRB00010793

Name and address of Organization Relying on the Designated IRB (herea

Organization Name:
Address:

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

Has the Organization's FWA been extended to non-federally funde

☐ Yes ☐ No

The officials having signed below commit their Organization to
continuing reviews of submitted research; reviews of amendm
may involve risks to subjects or others; reviews of potential nc
protection regulations or with the requirements or determin

Reliance Agreements

•IRB Authorization Agreement

•Specifies responsibilities of reviewing IRB and relying organization

Agreement Types

•BRANY IRB template

•Relying organization's template

•Use of SMART IRB reliance

Agreement Scope

•Agreement to cede to BRANY IRB for review of all studies using the VPR Cancer Linkage System

More About Local Context

Local Registry/IRB requirements

- Local laws, regulations, policies, standards
- Other local factors relevant to the research being conducted
- Local SOPs or requirements for releasing data from the registry
- BRANY IRB will establish workflows in its review process to ensure adherence to local requirements

More About Local Context

Do Registry Activities for the Study Using VPR-CLS Require IRB Approval?

- When is the local registry considered involved in the Study Using VPR-CLS ?

- When is a local registry considered engaged in the research?

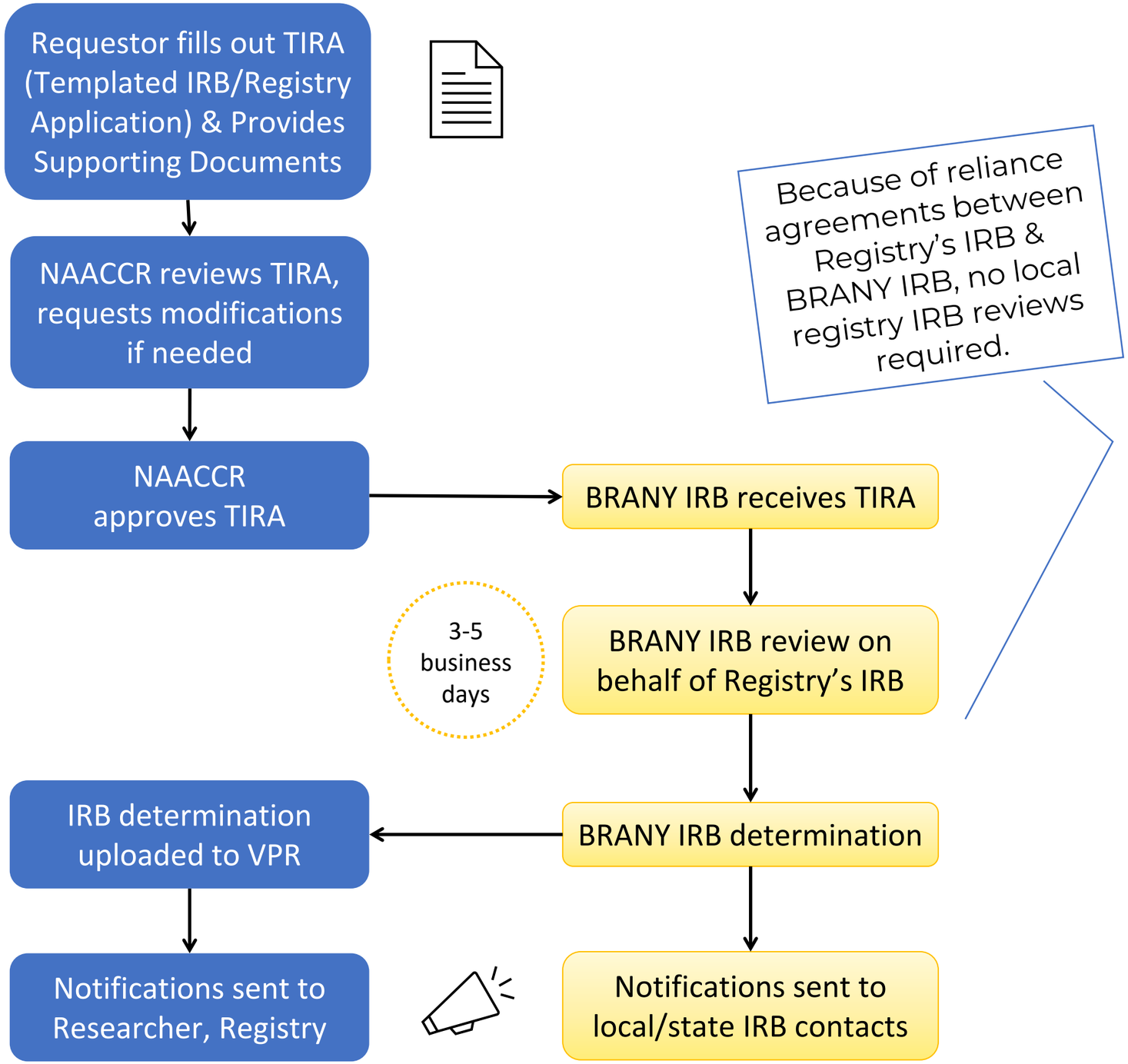
  - Federal funding involved for the study

  - The local registry intervenes with human subjects for the study

  - If the activity is limited to release of data, the registry is not engaged in the research, and IRB approval is not required by regulation (but may be required by local registry SOPs).

How Does BRANY IRB Fit Into the Existing Process?

Foundational Step:
Reliance Agreement established between Registry's IRB and BRANY IRB



Responsibilities of Involved IRBs

Researcher's Institutional IRB	BRANY IRB	Cancer Registry Local/State IRB
Provide IRB review for Researcher's overall study (including references to VPR-CLS linkage)	Provide IRB review (exempt or expedited) for VPR-CLS linkage component of study, if needed	Cede review to BRANY IRB for VPR-CLS linkage component of study
Review any changes or reportable events related to overall study	Review any changes or reportable events related to the VPR-CLS linkage component of the study	Receive notifications of BRANY IRB approval for any changes or reportable events related to the VPR-CLS linkage component of the study
Perform continuing approval for the overall study	Obtain progress reports for the VPR-CLS linkage component of the study	Receive notifications of BRANY IRB review of progress reports for the VPR-CLS linkage component of the study

Questions?

Please contact the BRANY IRB team:

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Raffaella Hart

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