NAACCR Summer Forum

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BRANY IRB as Central IRB for Review of VPR-CLS Linkage Requests: Purpose, Progress and Plans for 2022

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Agenda

- Central IRB (CIRB): What is a CIRB and why use one?
- About BRANY IRB
- BRANY's progress to date
- FAQs
- Plans for the year to come

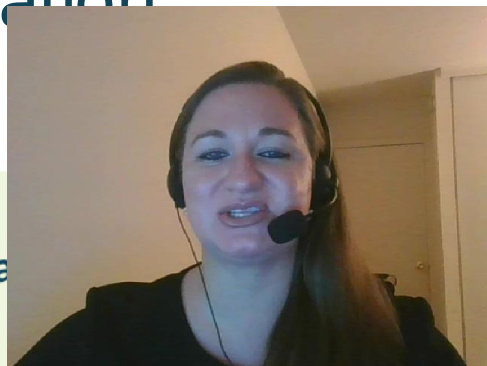
What is a CIRB?

A Central IRB (CIRB) is the IRB that conducts reviews on behalf of all study sites that agree to participate in the centralized review process.

2018 Revised Common Rule requires the use of a single IRB for cooperative research.

Why use a CIRB for NAACR VPR-CLS?

- Streamline process for the requesting researcher and each involved registry and their IRB
- Leverage existing VPR-CLS application process to perform a single, centralized IRB review that covers all agreeable registries
- Decreasing administrative burden and time to study initiation



Why BRANY IRB? Look to Our History

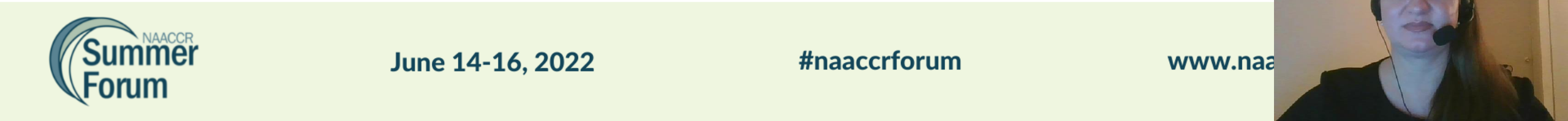
- Biomedical Research Alliance of New York LLC
- Organized in 1998
  - NYU School of Medicine
  - Montefiore Medical Center
  - Icahn School of Medicine at Mount Sinai
  - Northwell Health
- Approximately 1600 active research studies (35% expedited review)
- Approximately 200 exempt per year
- Over 100 employees

Follow BRANY IRB's Approach

- BRANY IRB has developed its infrastructure to adhere to the highest standards and ensure regulatory compliance
  - Dedicated Project Manager
  - Coordination of IRB Reliance Agreements
  - Efficiency & Flexibility
  - Strong communication
  - Expert Committee & IRB Staff

BRANY IRB: Committed to Excellence

- Accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP)
  - December 2019
  - December 2014
  - December 2009
  - December 2006
- Partnership of Human research Protections (NCQA & JACHO)
  - April 2004



Progress to Date

Meetings

IRB Authorization Agreements

Local context

First review completed

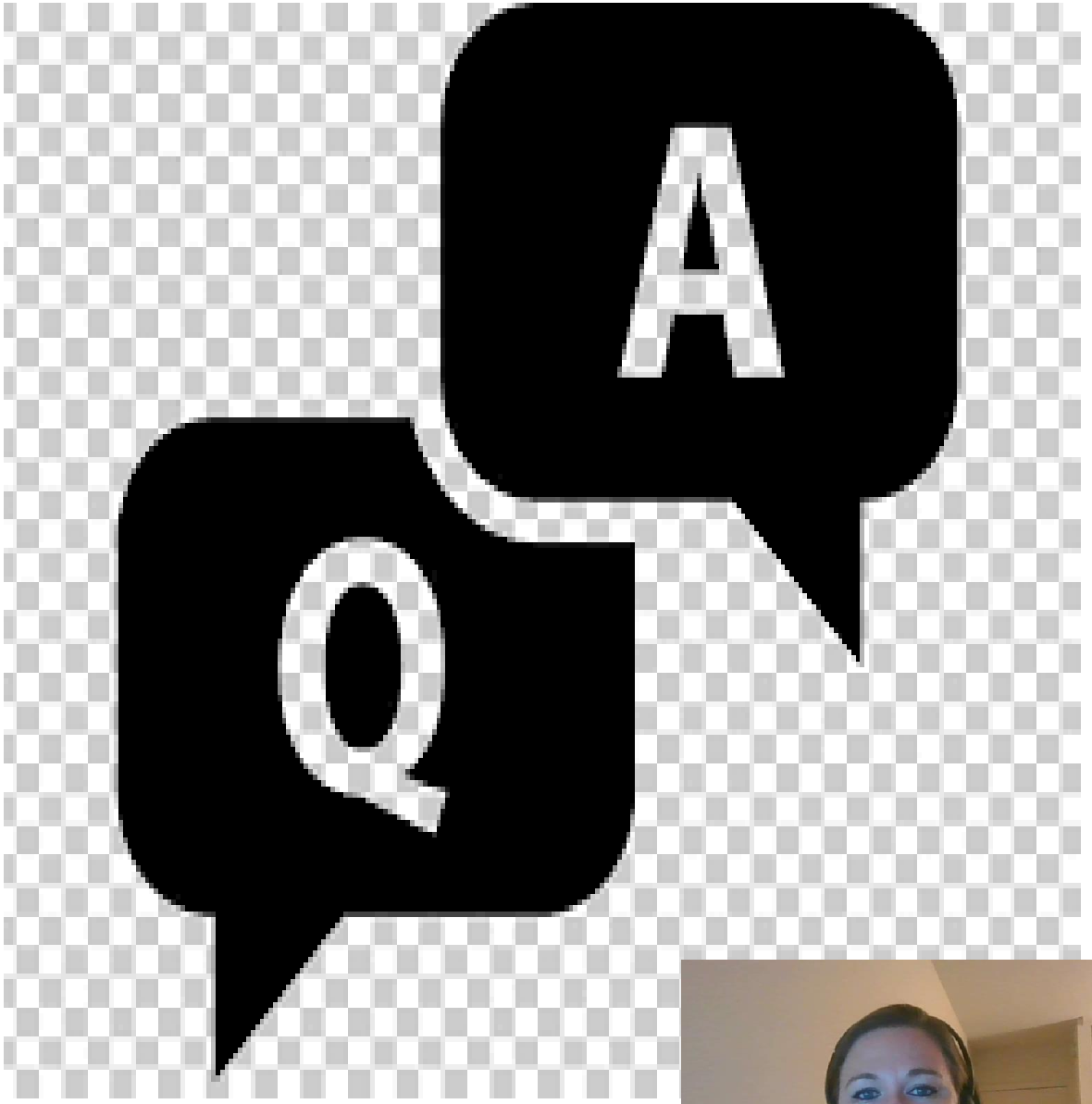
Meetings

- Arizona
- California
- Connecticut
- Louisiana
- Maine
- Massachusetts
- Michigan
- New Jersey
- New Mexico

- Ohio
- Oklahoma
- Oregon
- Puerto Rico
- Rhode Island
- Washington
- South Carolina
- Texas

FAQ

1. What is the VPR-CLS
2. Why use a CIRB? What is the benefit?
3. How do researchers submit a request to BRANY IRB?
4. What will BRANY IRB be doing?
5. Why does BRANY IRB collect local research context information?
6. What is an IRB Authorization Agreement?
7. Will there be any cost to use the CIRB?
8. Whom do I contact at BRANY with additional questions?



Reliance Agreements

Reliance Agreements	IRB Authorization Agreement
	Specifies responsibilities of reviewing IRB and relying organization
Agreement Types	BRANY IRB template
	Relying organization's template
	Other template agreements (e.g., SMART IRB)
Agreement Scope	Agreement to cede to BRANY IRB for review of all studies using the VPR Cancer Linkage System

Executed Reliance Agreements

Georgia Department of Public Health / Georgia Center for Cancer Statistics	University of Hawai'i / Hawai'i Tumor Registry	State of Maine Department of Health and Human Services	University of New Mexico Health Sciences Center Human Research Review Committee / New Mexico Tumor Registry
Oklahoma State Department of Health / Oklahoma Central Cancer Registry	Oregon Health Authority - Public Health Division / Oregon State Cancer Registry	University of Puerto Rico / Puerto Rico Central Cancer Registry	Rhode Island Department of Health / Rhode Island Cancer Registry

Understanding Local Context

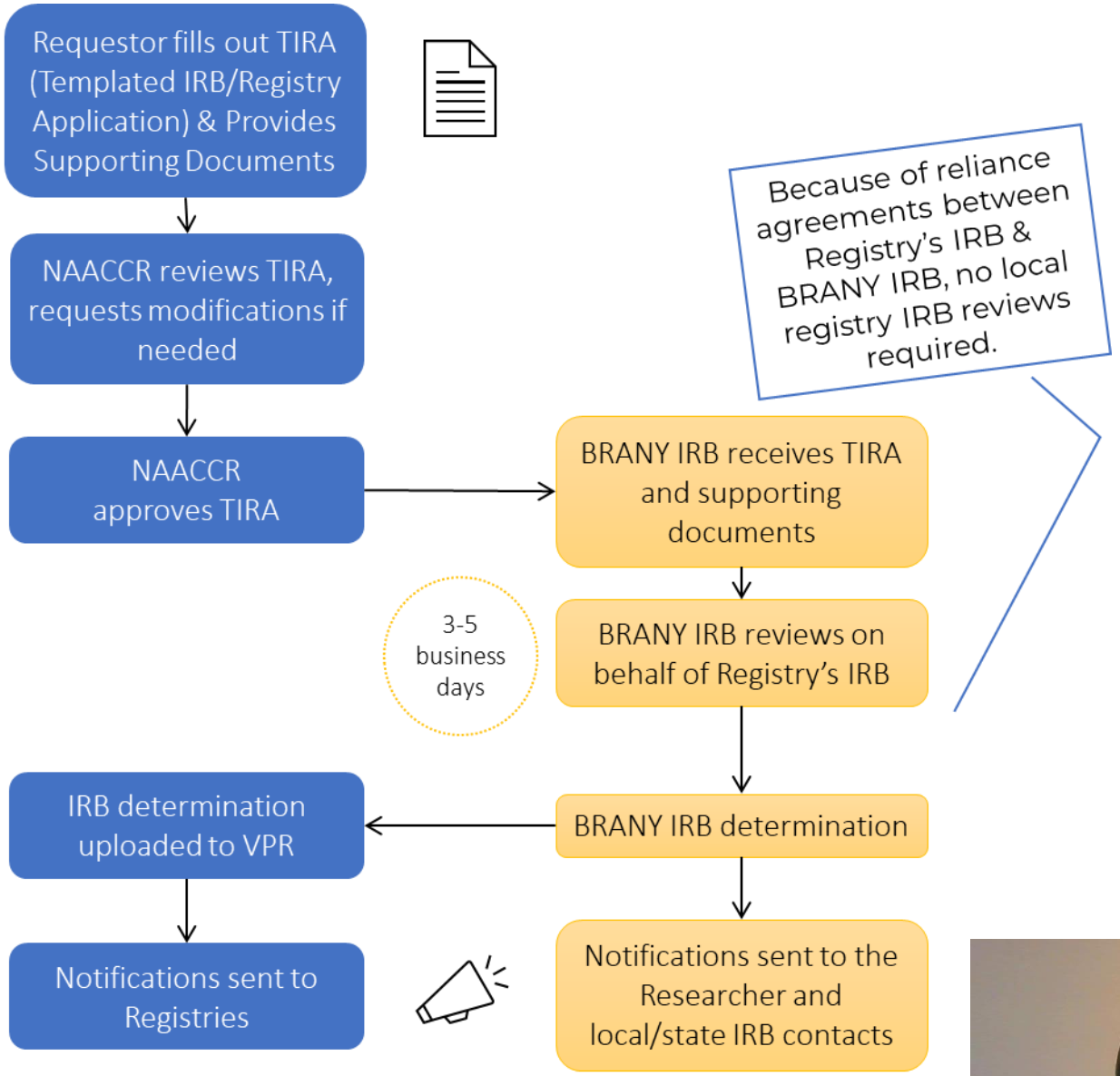
- Requirements to allow release of data from the local registry
- Determine which registry activities require IRB approval
- What kinds of communication about ceded IRB review does the registry and/or IRB require?
  - Notification that BRANY IRB has received a submission involving the registry
  - Outcome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

Pilot Test – The Sister Study

- Study led by the National Institute of Environmental Health Sciences
- Apply the CIRB process with select registries involved in The Sister Study
- Identify factors that need to be considered when developing the VPR functionality to support the CIRB process.
- TIRA received by BRANY IRB on May 26th and IRB review was completed on June 1st

How Does BRANY IRB Fit Into the Existing Process?

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



Expectations for 2022

- Continue- Teleconferences
- Obtain- IAAs and LRCs
- Refine- Workflow & SOPs
- Launch- BRANY IRB Webpage for VPR-CLS
  - Useful Forms and Links, FAQ's, Contact Information, etc.
- Review Future Requests

Questions?

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