Creighton UNIVERSITY

# CU IRB and Me:

## CRITERIA FOR APPROVAL (PART 3 OF 3)

# Agenda

- Criteria for approval
- CITI webinars
- IRB website
- Revised guidance documents
- Metrics
- Q & A

# Criteria for IRB approval of Research 45 CFR 46.111

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result
- Selection of subjects is equitable
- Informed consent will be obtained and documented (unless waived) accordingly
- There are adequate provisions for data monitoring to ensure safety of subjects if appropriate
- There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data if appropriate
- There are additional safeguards to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence

# Criteria for IRB Approval of Research – 45 CFR 46.111

6. **When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

This criterion for approval is associated with the Belmont principle of **Beneficence**.

The principle of Beneficence encompasses two general rules:

1. Do not harm.
2. Maximize possible benefits and minimize possible harms.

By requiring a plan for monitoring data to ensure the safety of subjects, the regulations are operationalizing the "minimize harms" aspect of Beneficence. This ensures that if a study becomes unexpectedly risky or if a clear benefit is identified early, the research can be modified or stopped to protect the participants.

# Data Monitoring to Ensure Safety of Subjects

**Things to consider:**

- Is there a data safety monitoring plan (DSMP)?
  - The DSMP must be developed to fit the design and risk profile of the research. It should include, as appropriate, elements such as: specific data that will be reviewed, frequency and duration of review, who is conducting the review, conditions under which specific subjects should be withdrawn, and as appropriate based on the design and risk profile of the research, the conditions under which the study will be halted (that is, study stopping rules based on efficacy, toxicity and futility)
- Is there a data safety monitoring board (DSMB)?
  - A formal DSMB is recommended for: Phase III or high-risk Phase II clinical trials, research involving a large study population or multiple study sites, vulnerable populations that could benefit form closer monitoring, or research that involves an intervention
- Is the monitoring plan appropriate and adequate?
  - The IRB will consider the adequacy of the plan based on the design and risk profile of the research.

# Criteria for IRB Approval of Research – 45 CFR 46.111

7. **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

- This criterion is primarily associated with the Belmont principle of ***Respect for Persons***.
- This principle emphasizes that individuals should be treated as autonomous agents. A key part of respecting a person's autonomy is honoring their right to control what happens to them—including who has access to their personal information and under what circumstances.
  - **Privacy:** This refers to a person's right to control the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with others.
  - **Confidentiality:** This refers to the researcher's agreement with the participant about how their identifiable private information will be handled and protected from unauthorized release.

# Privacy and Confidentiality of Subject Data

**Things to consider:**

- Protection of Privacy:
  - Does the PI and other personnel have ethical access to the participant's private identifiable information?
  - Are the methods used to identify and contact the participants minimize the risk to privacy?
  - Is the location where Informed consent will be obtained conducive to the privacy interest of the participants?
  - Are the research activities performed in a private place?
- Protection of Confidentiality:
  - Are the physical and/or electronic safeguards and security measures for the entry, storage, and transfer of data adequate?
  - Is there adequate justification for sharing identifiable private information? Is the PHI shared in a manner that is HIPAA compliant?
  - Is there a plan to destroy the data when no longer needed?

# Case Study

A study will qualitatively examine and describe the ways in which trans people experience sexuality and explore how trans individuals describe the connection between gender and sexuality.

Individual and focus group interviews will be conducted at the university faculty lounge.

Researchers will use personal cell phones to audio-record the individual and focus group interviews.

# Case Study Quiz

What are some study design changes that might better protect the privacy of participants and the confidentiality of their data? (select all that apply)

- ❑ Conduct individual and focus interviews in a private space
- ❑ Store all research data on a personal computer connected to public Wi-Fi
- ❑ Notify focus group participants not to discuss what is said by others
- ❑ Use a digital voice recorder to record the interviews

# Criteria for IRB Approval of Research – 45 CFR 46.111

8. **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**

- The requirement for additional safeguards for vulnerable populations is primarily associated with the Belmont principle of **Respect for Persons**.
- The Belmont Report breaks this principle into two distinct moral requirements:
  - **Individuals should be treated as autonomous agents.**
  - **Persons with diminished autonomy are entitled to protection.**
  - Because children, prisoners, or those with impaired decision-making capacity may have a restricted ability to provide truly voluntary informed consent, the principle of Respect for Persons demands that we provide **additional safeguards** to ensure their rights and welfare are protected.

# Additional Safeguards for Vulnerable Subjects

**Things to consider:**

- Are potentially vulnerable populations involved?
- What kind of vulnerabilities?
  - Are they intrinsic vulnerabilities (e.g., limitation in mental capacity because of age or illness)?
  - Are the vulnerabilities by reason of extrinsic factors (e.g., socioeconomic structures or other social determinants)?
- What additional safeguards will you put into place for each vulnerable population in your study?
  - i.e., Parental permission for a study that involves children

# Additional Requirements for Reviewing Subpart Populations

**45 CFR 46**

- Subpart B – Pregnant women and fetuses, neonates (§ 46.201 through § 46.207)
- Subpart C – Prisoners (§ 46.301 through § 46.306)
- Subpart D – Children (§ 46.401 through § 46.409)

# CITI Webinars

**Available webinars relevant to today's topics**

- Working with Your IRB (ID: 317832)
- Advance Research Directives Tools for Supporting People Who Lack Decision-Making Capacity (ID:317780)
- Data Management and Security for Student Researchers: An Overview (ID:317857)
- Gender and Sexual Minorities (GSM) in Human Subjects Research (ID:317861)
- Health Disparities: Promoting Equity and Diversity in Clinical Research (ID:317821)
- Privacy and Ethical Considerations for Connected and Automated Vehicles (CAVs) (ID:317850)
- Research Equity and the Part We Play (ID:317870)
- Utilizing Outside Experts on the IRB (ID:317761)
- Why Sex Matters from Research to Patient Care (ID:317775)

# CU IRB Website


https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb

# Revised Guidance Documents

**Templates**

- Revised Informed Consent Template
- Revised Parent/Guardian Permission Template
- Revised Assent for Ages 7-12 Template
- Revised Assent for Ages 13-18 Template

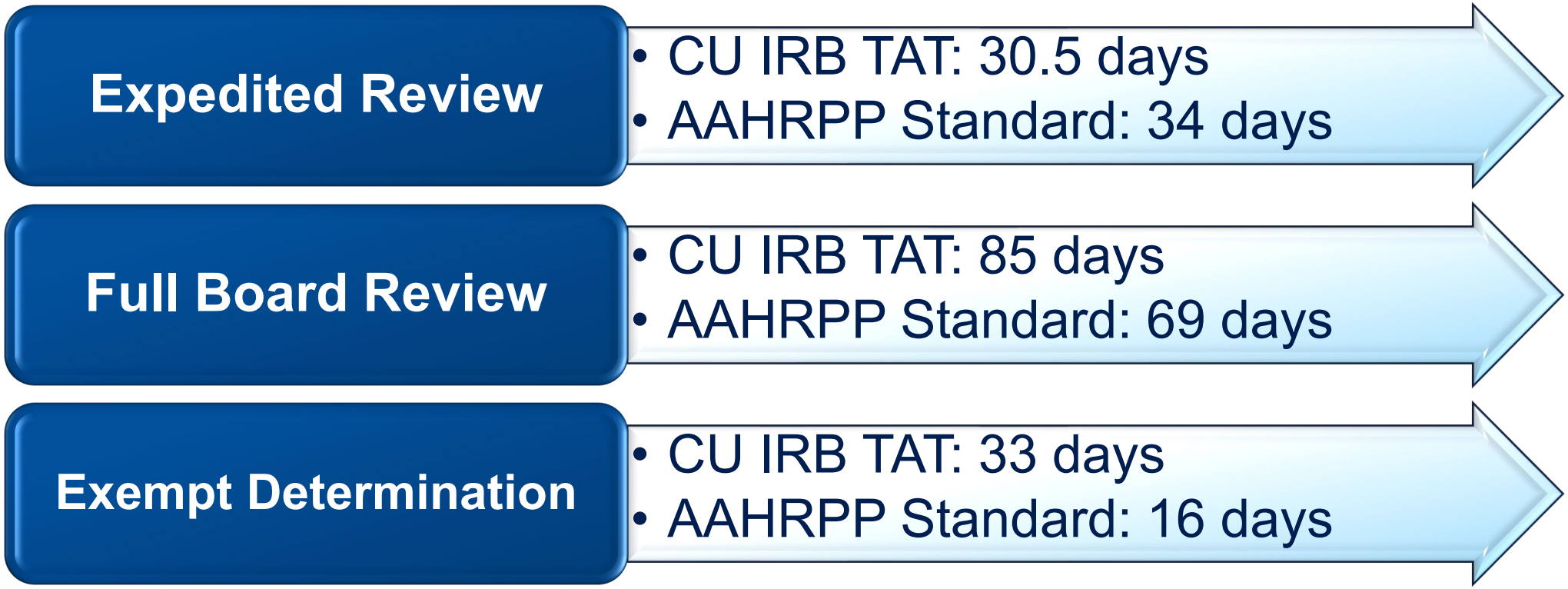
*** The Senior IRB Administrators will return submissions if these documents are not on the most updated template*

- Revised HIPAA authorization
- Protocol Template
- NHSR/QI Proposal Template **NEW**
- Checklist: Does my Project Require IRB Review?

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb/investigator-resources

# Recent Metrics

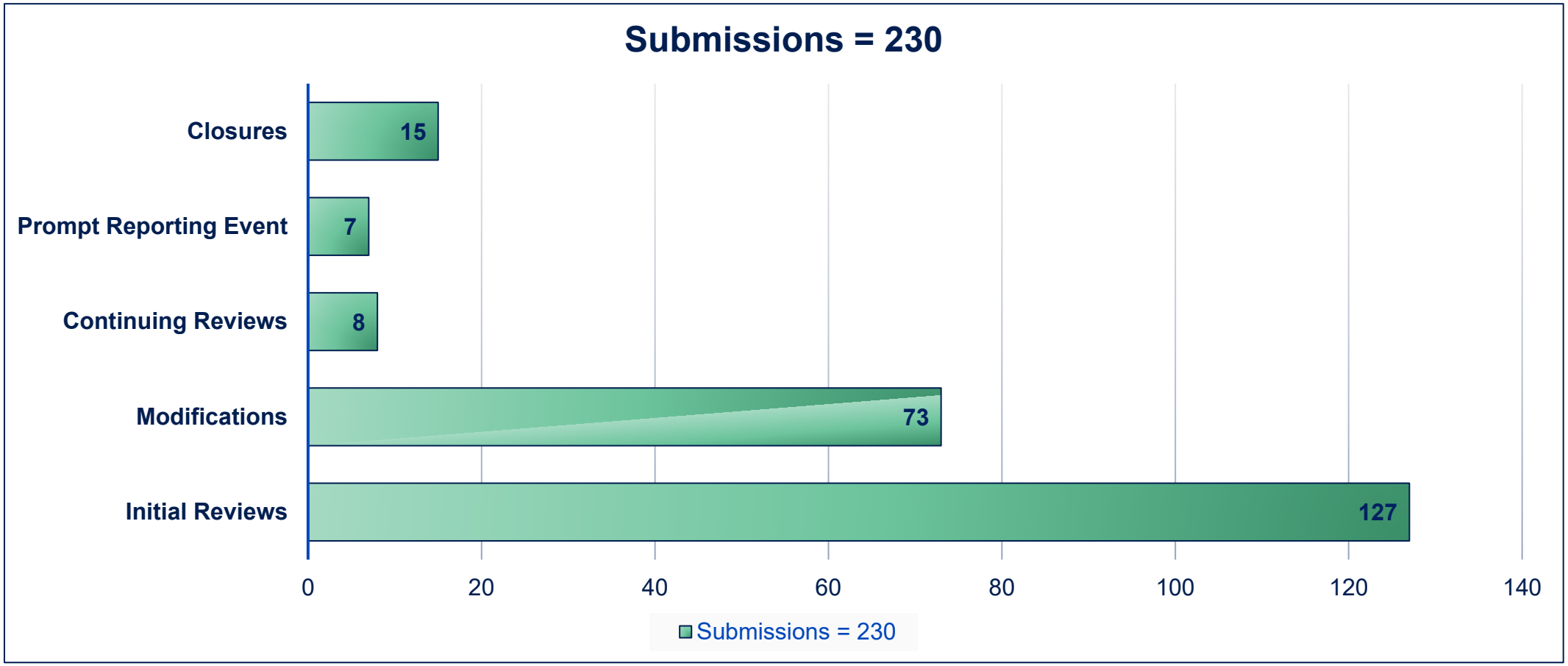
Turnaround time (TAT) data from **submission** to initial approval (January 2026 through March 2026).
*Note: TAT includes days with investigators.*




*AAHRPP = Association for Accreditation of Human Research Protection Programs, Inc.*

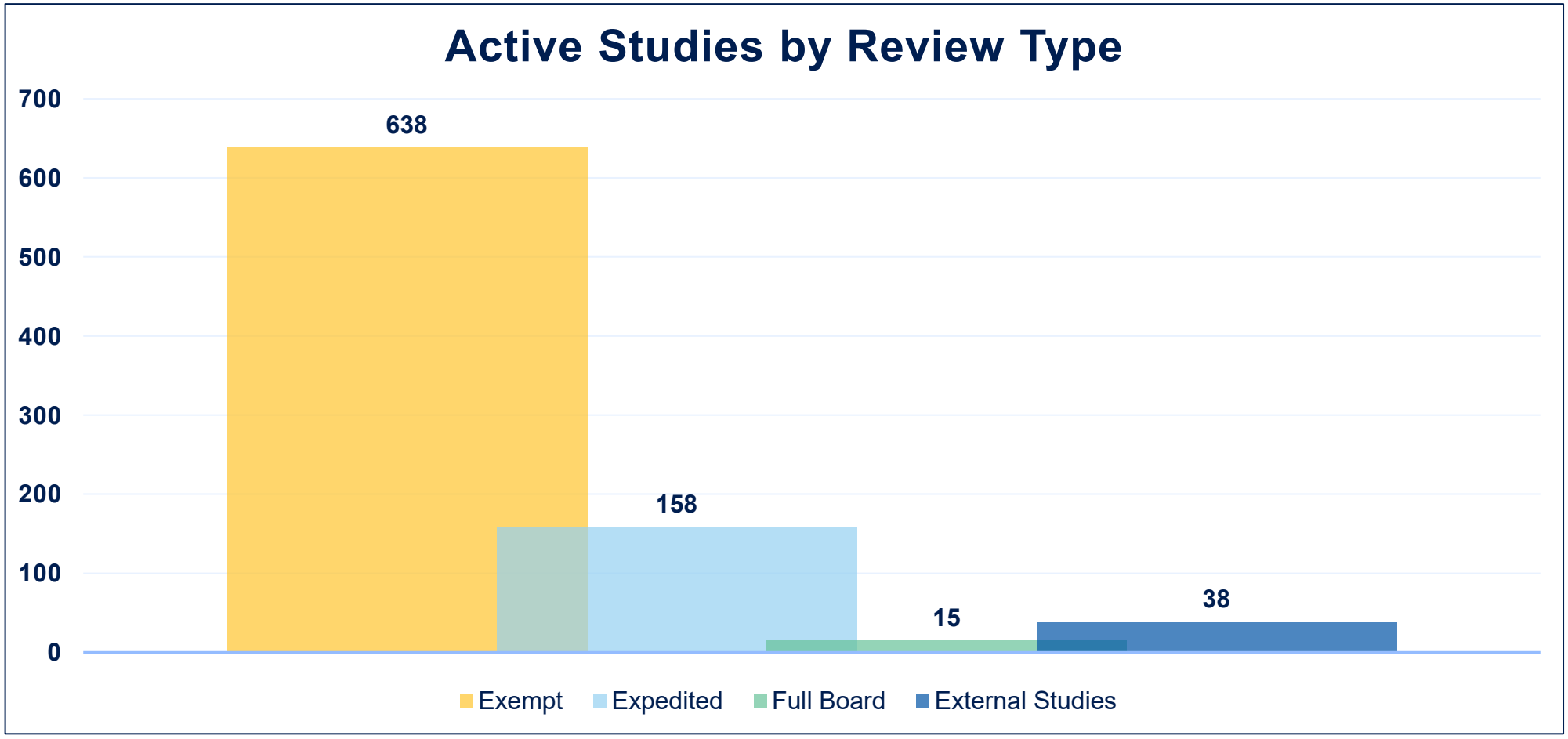
# Recent Metrics

Total application submissions – to date January 2026 through March 2026:



# Recent Metrics

The CU IRB currently reviews and monitors 849+ active studies.



# Help us help you

**Our goals**

- Provide meaningful education and guidance to the research community
- Support researchers for the lifetime of their studies

IRB Booking Page

Suggestions for future CU IRB and Me sessions

# Next CU IRB and Me Session: International Research on 20-May-26 at 12 PM (Central)

# Q & A

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# *Thank you.*

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