2023 "HRPP Innovations" Webinar Series

Human Research Protection Programs and the Open Science Movement

April 18, 2023

1:00 pm – 2:30 pm ET

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Association for the Accreditation of Human Research Protection Programs, Inc.®

Format for 2023

Attendee Hub

- Livestreamed Content
- Live Q&A
- Chat/Discussions

Webinar Sessions

- Three Webinars: April, July, November
- One Attendee Hub

Community

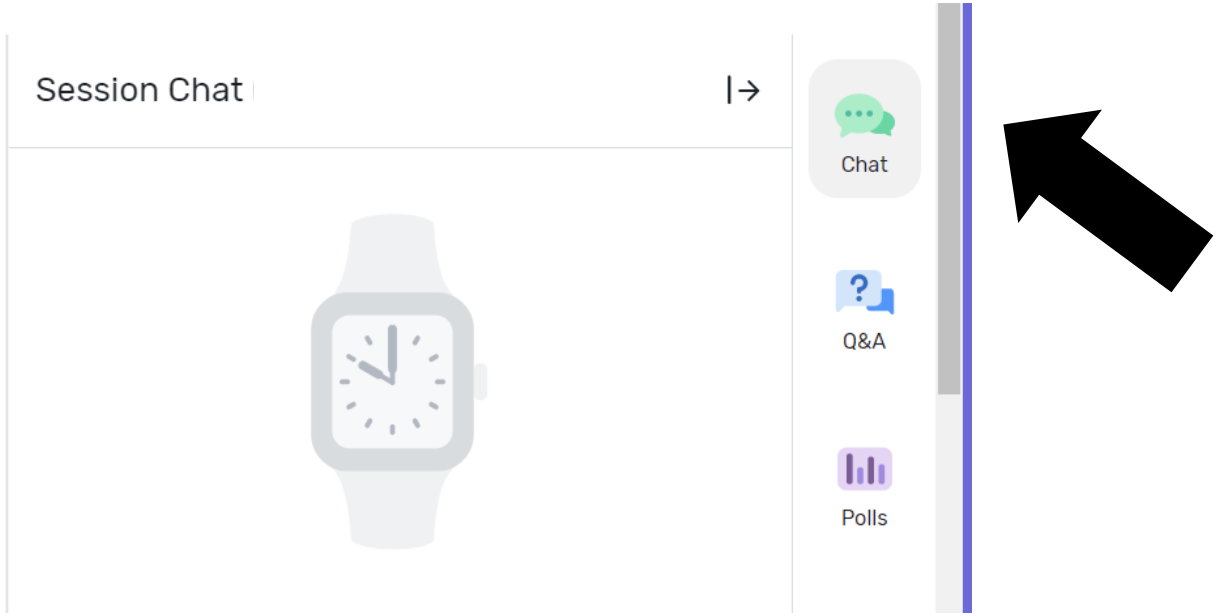
- Continue Discussions after Webinars Conclude
- Check Upcoming AAHRPP Events
- Resources from Speakers

On-Demand Content

- Webinar Recordings on Hub
- Available for the Whole Year

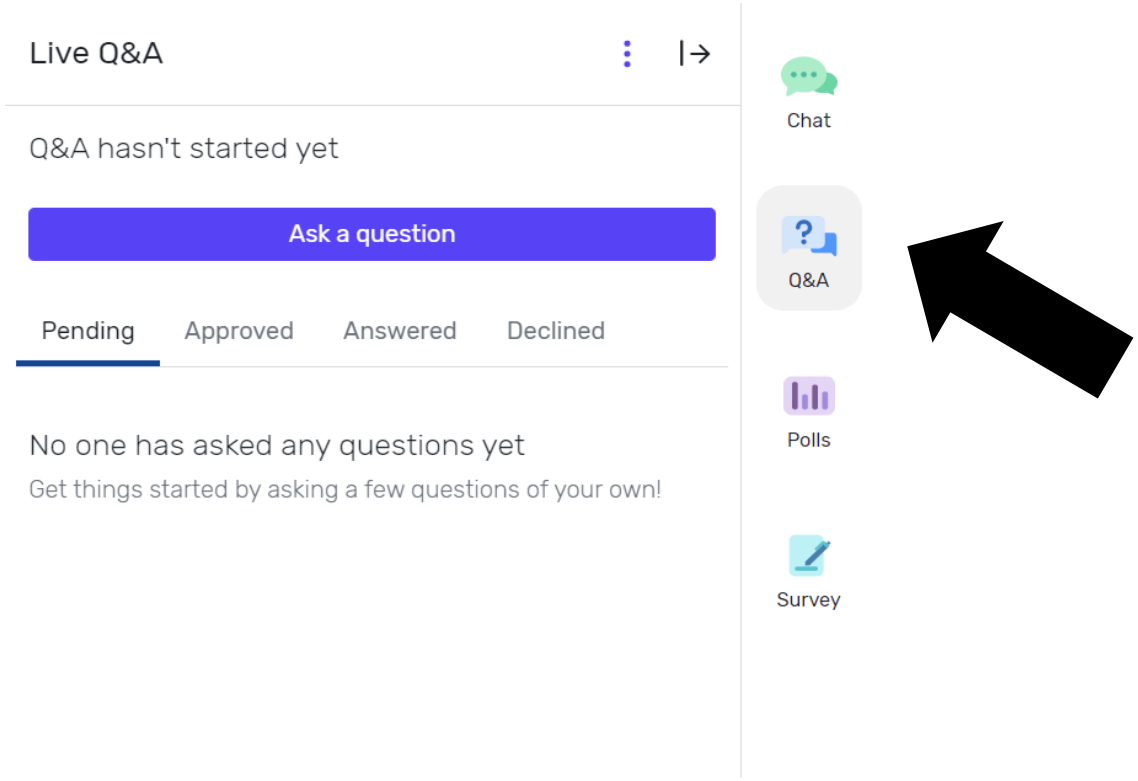
Chat Feature

To chat with your colleagues before and after the session, or if you have technical questions, use the “Chat” icon



Questions

To ask questions about the topic for the presenters, please use the “Q&A” icon:



Join Us for the 2023 AAHRPP Annual Conference

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Presenter Introductions

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Nichelle Cobb, PhD

Senior Advisor for Strategic Initiatives
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Sean Grant, DPhil, MSc

Research Associate Professor

University of Oregon

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Benjamin Silverman, MD

Senior IRB Chair, Human Research Affairs

Mass General Brigham

Baseline Poll

- Before registering for this webinar, how aware were you of the open science movement or open science practices?
  - I am very familiar with the open science movement/practices
  - I was vaguely aware of the open science movement/practices
  - Never heard of the open science movement/practices before registering for this webinar
  - Unsure

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2023 AAHRPP Webinar Series

Exploring the Intersection of Human Research Protections and Open Science Practices

Dr. Sean Grant

Research Associate Professor

HEDCO Institute for Evidence-Based Educational Practice

College of Education, University of Oregon

Acknowledgments

- **Core Collaborator**
  - Kathryn Bouskill, RAND Corporation
- **Funding**
  - Robert Wood Johnson Foundation (#74420)
- **Honoraria**
  - US Office of Planning, Research, and Evaluation
  - Berkeley Initiative for Transparency in the Social Sciences

What are Open Science Practices?

Design	Conduct	Dissemination	Archiving
Registration	Research Notebook	Transparent Reporting	Data Sharing
Protocol	Version Control	Preprint Sharing	Code Sharing
Analysis Plan	Dynamic Document	Open Access	Materials Sharing

Grant et al. (2022)

Open Science is Becoming "Normal"

HELIOS

BRIEFING ROOM

OSTP Issues Guidance to Make Federally Funded Research Freely Available Without Delay

AUGUST 25, 2022 • PRESS RELEASES

Today, the White House Office of Science and Technology Policy (OSTP) updated U.S. policy guidance to make the results of taxpayer-supported research immediately available to the American public at no cost. In a memorandum ↗ to federal departments and agencies, Dr. Alondra Nelson, the head of OSTP, delivered guidance for agencies to update their public access policies as soon as possible to make publications and research funded by taxpayers publicly accessible, without an embargo or cost. All agencies will fully implement updated policies, including ending the optional 12-month embargo, no later than December 31, 2025.

Analysis of OHRP Documents

Why institutional review boards should have a role in the open science movement

Sean Grant[a,1] and Kathryn E. Bouskill[b]

Open science involves the use of practices across the research life cycle that facilitate the transparency, reproducibility, and availability of scientific products and output. Prominent open science practices include registration of study protocols and preanalysis plans; materials, data, and code sharing; and publication of summary findings in open access outlets (1). To achieve openness as the default approach, initiatives are trying to use a systems approach to engage stakeholders—namely, scientific journals, funding agencies,

https://www.pnas.org/doi/10.1073/pnas.1916420116

Open Science is Relevant to IRBs

- **IRBs can influence investigators' ability to practice open science in their human subjects research**
- **IRBs will be impacted by move to "open" science**
  - Growth in practices that influence level of review
- **IRB review provides an opportunity to intervene early (and throughout) the research lifecycle**
  - Potential to support open science practices by influencing researchers to consider them

Doernberg & Wendler (2016), Meyer (2018)

Survey and Interview Methods

- **Approached 253 R1/R2 universities with active IRB**
- **Questions based on ethical principles/regulations**
  - Relevance, policies, procedures, guidance, templates, expertise, and IRB oversight
- **Followed by semi-structured interviews**
  - Identify facilitators/barriers to enact behavior based on capability, motivation, and opportunity

Grant & Bouskill (2019), Michie (2014)

Participant Characteristics

Characteristic	Survey	Interview
Sample Size	132	33
IRB Chair	78%	64%
Certified Professional	17%	24%
Electronic System	84%	82%
Evaluate Clinical Trials	61%	58%
Accredited Program	53%	33%

Relevance of Open Science Practices: Declaration of Helsinki

- We would like to know the extent to which you agree or disagree with the following statements:
  - **Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.**
  - **Researchers have an ethical obligation to make publicly available the results of their research on human subjects.**

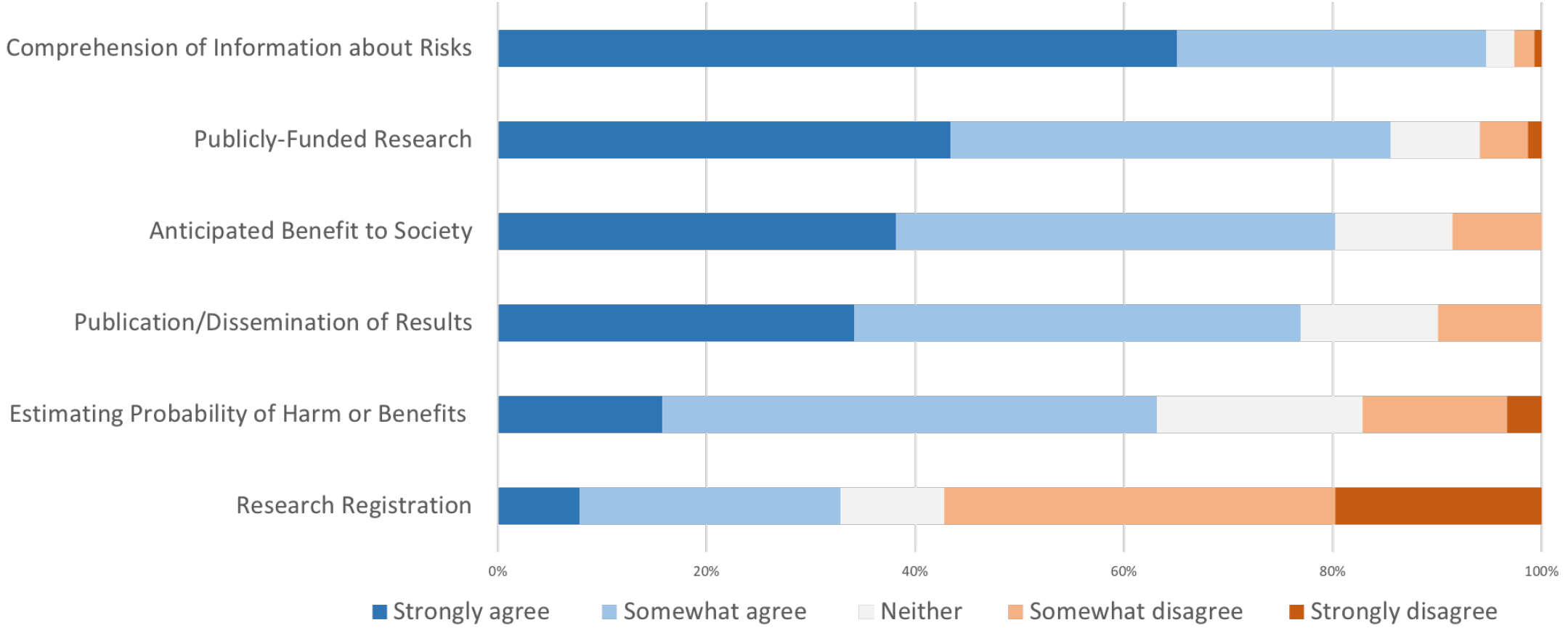
Relevance of Open Science Practices: Belmont Report

- **Investigators have an obligation to make sure that subjects adequately comprehend risk of breaches in confidentiality**
- **The products of publicly-funded research should be made publicly available in as open a manner as possible.**

Relevance of Open Science Practices: Belmont Report

- When results of a research study are not publicly available…
  - **Benefits to society (generalizable knowledge to be gained from research) are lost**
  - **IRB ability to accurately estimate the probability of harm or benefit of future studies is impaired**

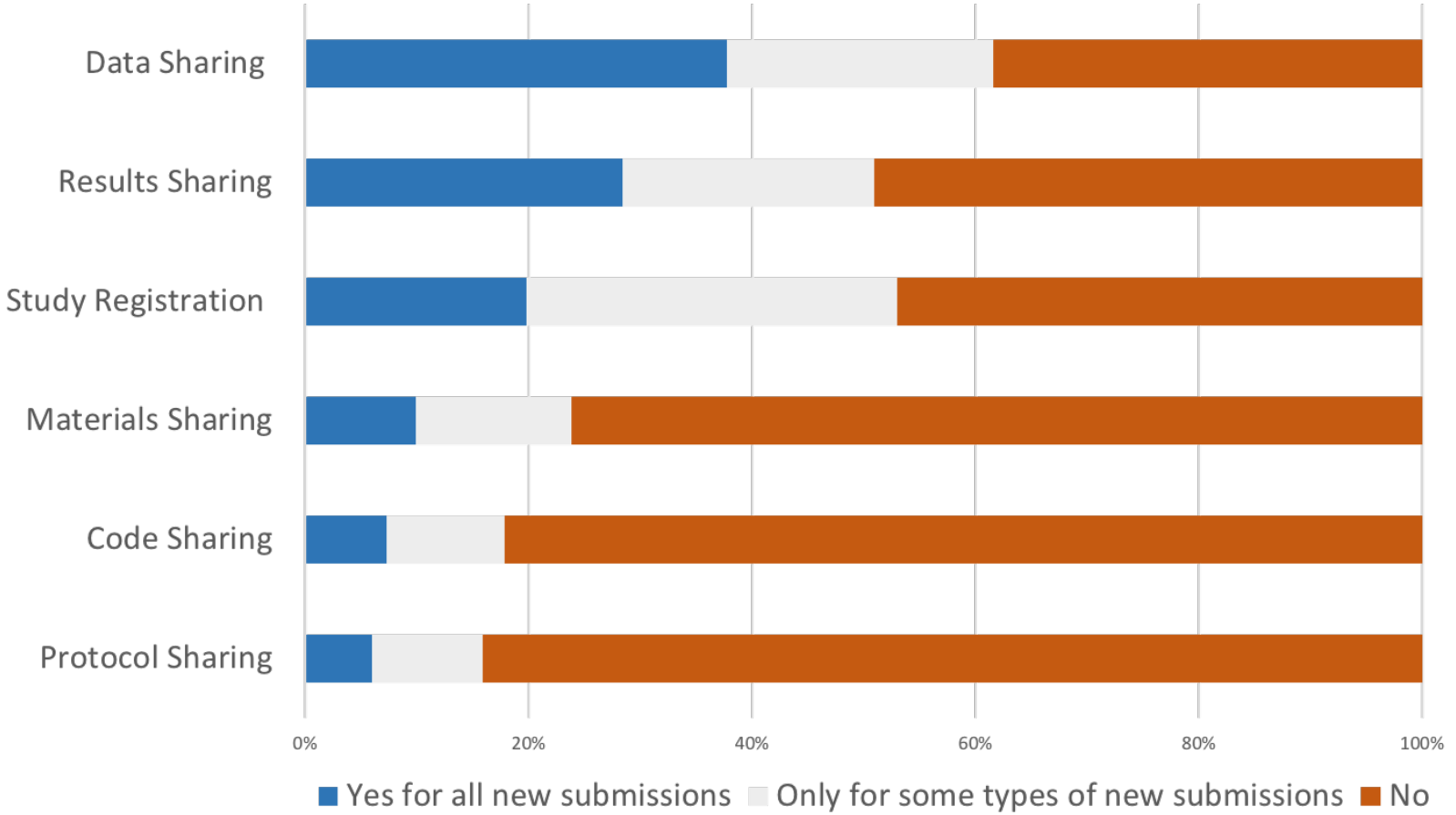
Relevance of Open Science Practices to Official Ethical Principles



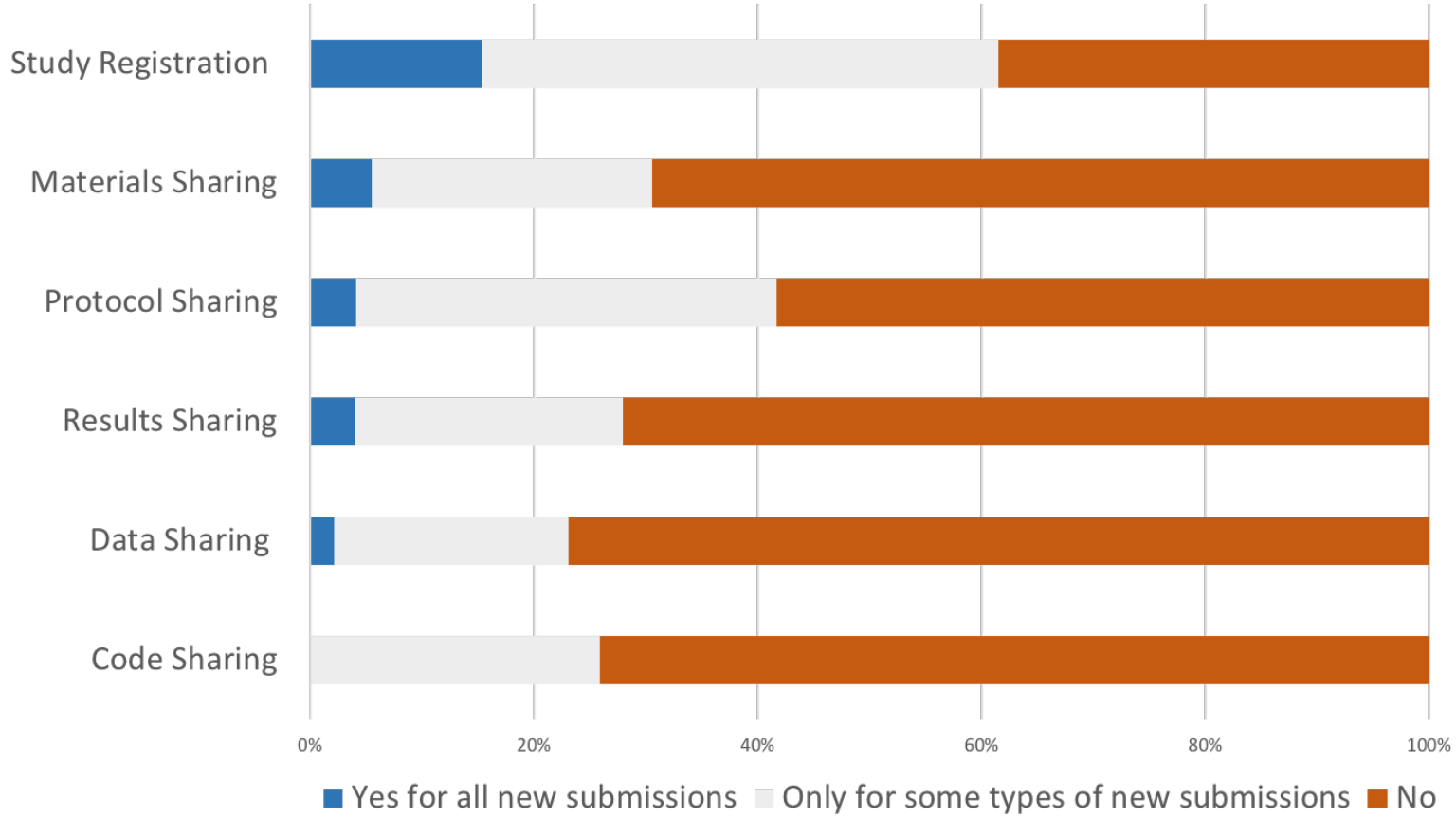
Proposed, Verifying, and History of Use of Open Science Practices

- **Proposed use (45 CFR 46.109: IRB Review of Research):** explicitly ask investigators to describe whether they plan to use an open science practice
- **Verifying use (45 CFR 46.109: IRB Continuing Review of Research):** among IRBs that ask about an open science practice, explicitly verify that plans have been followed
- **History of using (45 CFR 45.115: IRB Records):** IRB considers an investigator's history of implementing open science practices in previous studies when reviewing a new study submission

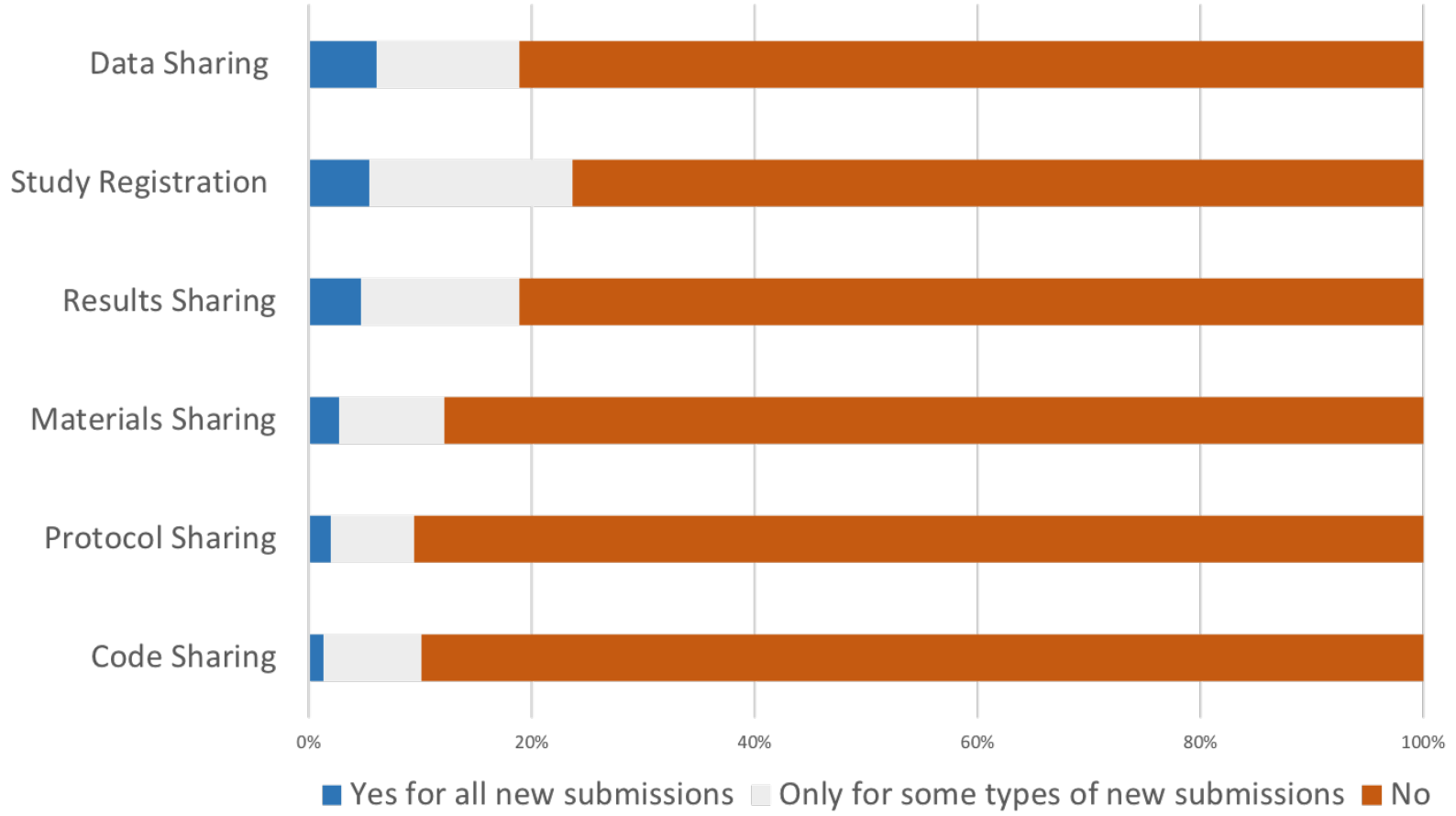
Ask Investigators about Open Science Practices



Verifying Use of Open Science Practices



History of Using Open Science Practices



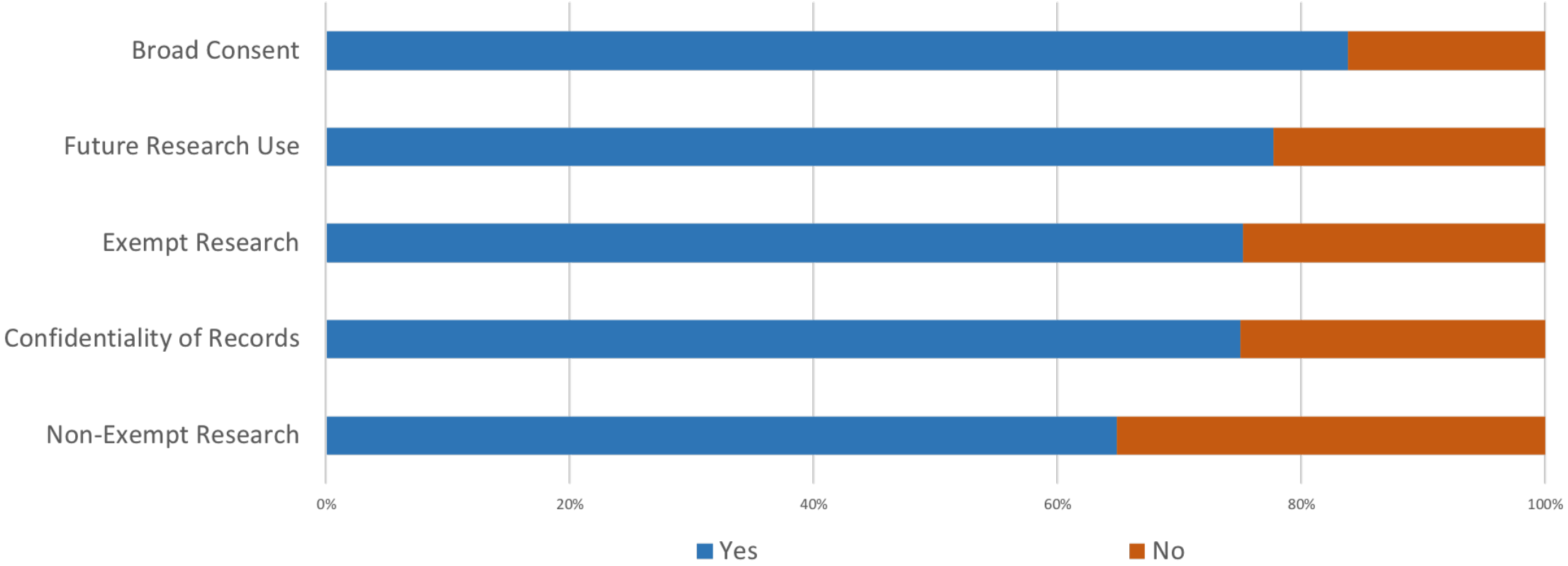
Guidance and Templates on Specific Open Science Practices in Regulations

- **Exempt Research (§46.104(d)(2)-(4)):** how to record information so identity cannot readily be ascertained
- **Non-Exempt Research (§46.111(a)(7)):** how to share data with adequate provisions to protect privacy/confidentiality
- **Confidentiality of Records (§46.116(b)(5)):** informed consent language on extent to which confidentiality will be maintained

Guidance and Templates on Specific Open Science Practices in Regulations

- **Future Research Use (§46.116(b)(9)(i)):** informed consent language on future research use of de-identified data
- **Broad Consent (§46.116(d)):** example broad consent form as alternative to traditional informed consent

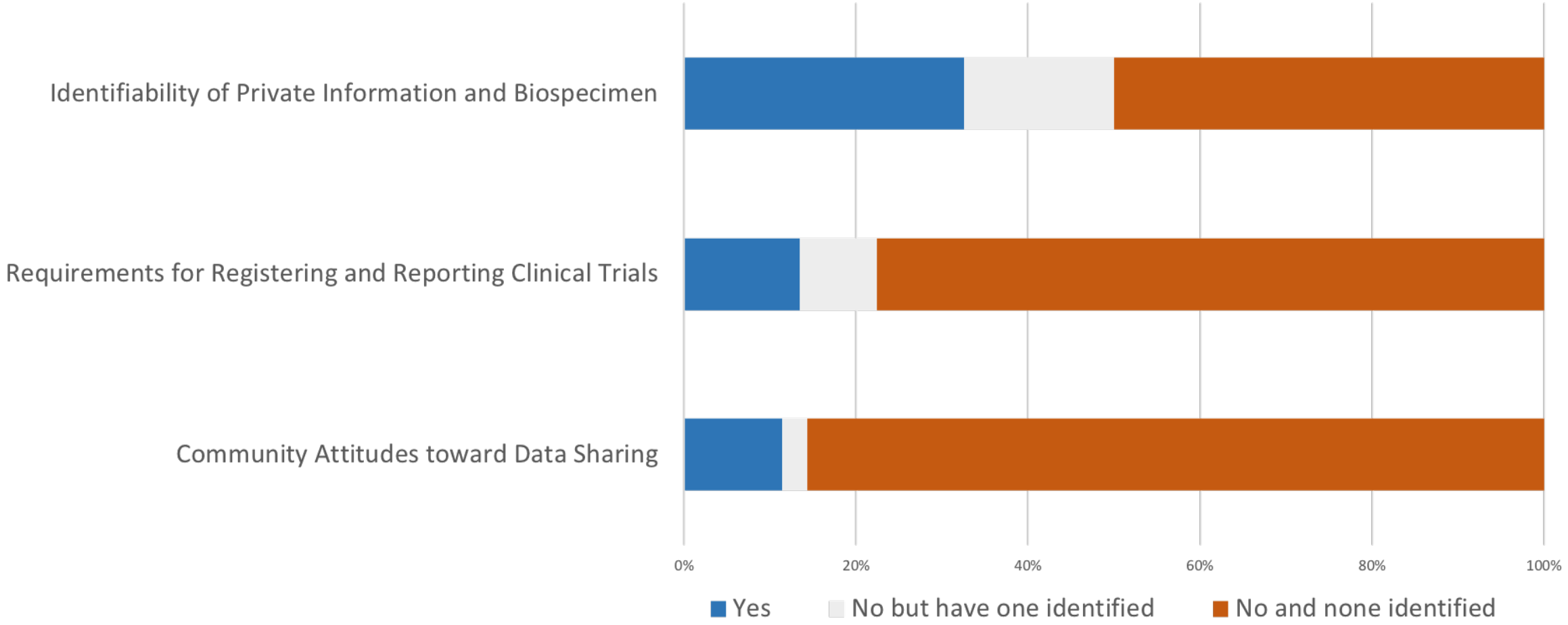
Guidance and Templates for Sharing Data



IRB Members and Consultants with Expertise in Open Science Practices

- **Identifiability of Private Information and Biospecimen (§46.102(e)(7)(i)(ii)):** through data matching, re-identification, and analytic technologies/techniques that generate identifiable data
- **Community Attitudes toward Data Sharing (§46.107(a)):** "sensitivity to community attitudes" as an important qualification to promote respect for IRB advice and counsel in safeguarding subjects
- **Requirements for Registering and Reporting Clinical Trials (§46.107(a)):** ascertain the acceptability of proposed research in terms of other applicable regulations/laws

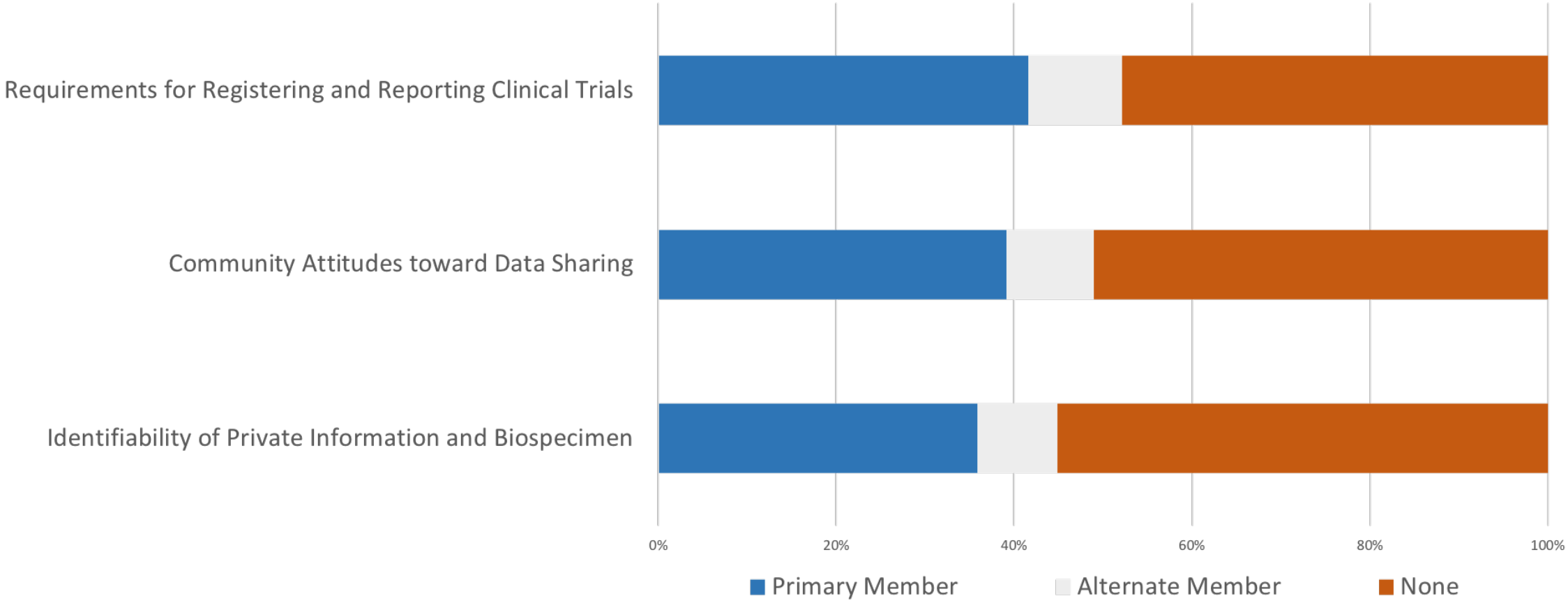
IRB Consultants for Open Science Practices



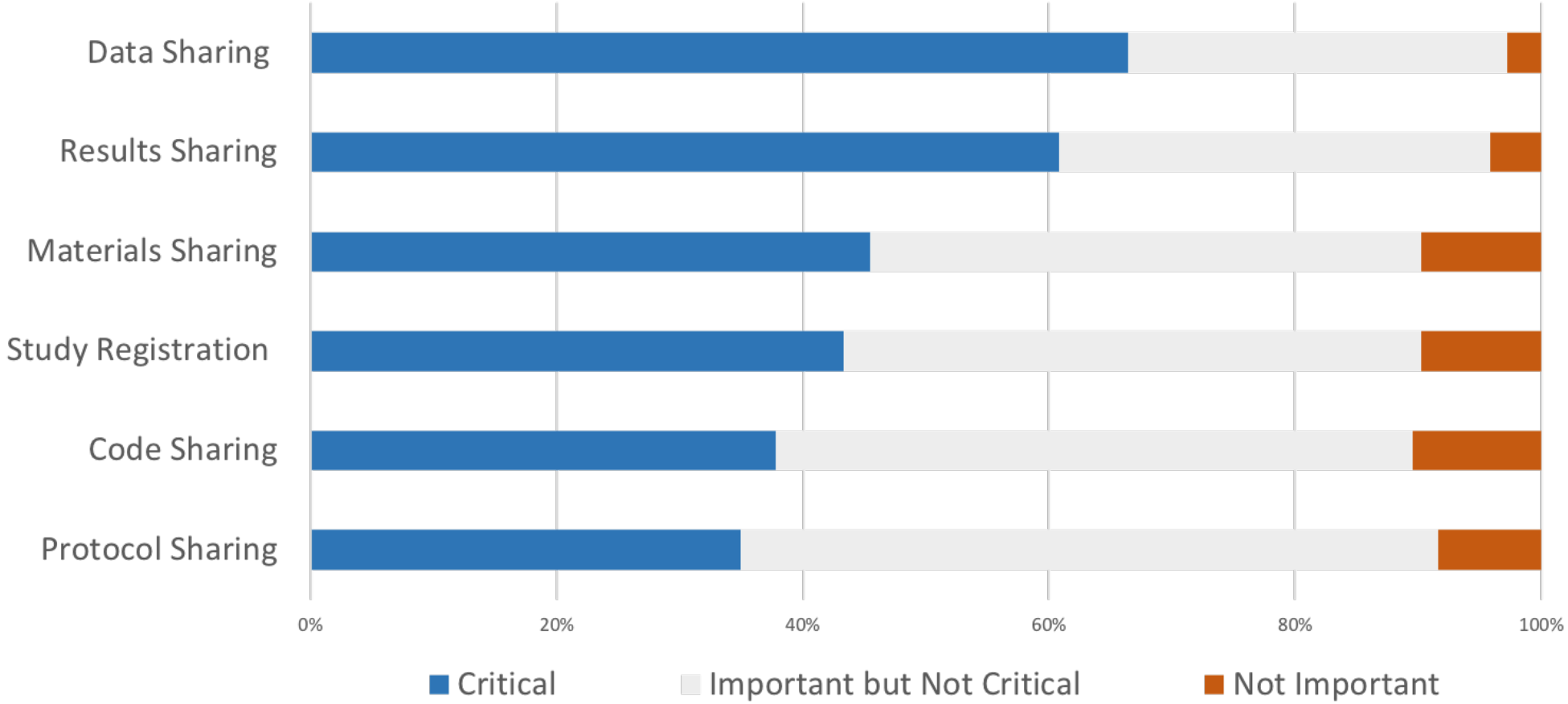
Oversight, Accreditation, and Certification on Open Science

- **Office of Human Research Protections:** authoritative guidance for IRBs on open science practices
- **Association for the Accreditation of Human Research Protection Programs:** incorporate standards into accreditation on open science practices
- **Public Responsibility in Medicine and Research:** incorporate competencies on open science practices in the Certified IRB Professional program

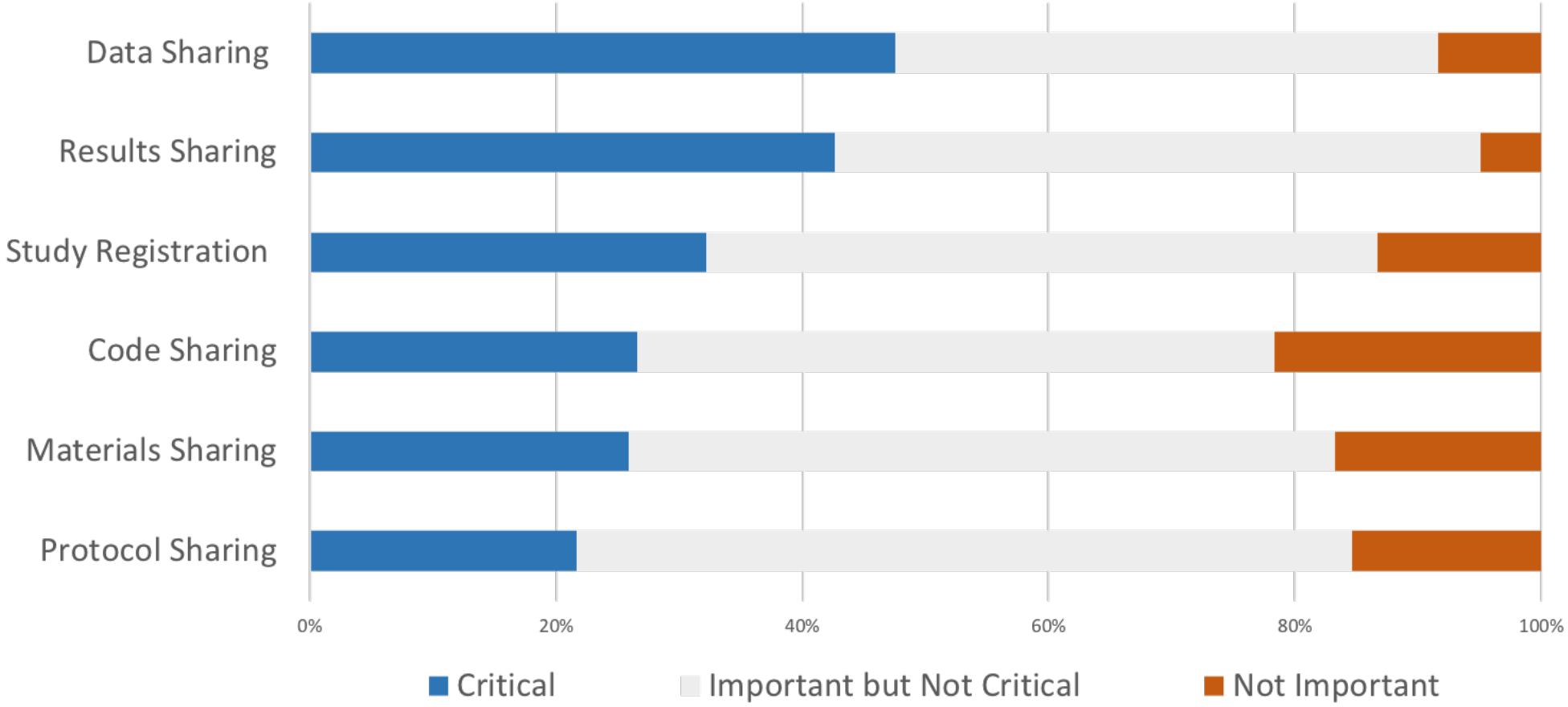
IRB Expertise in Open Science Practices



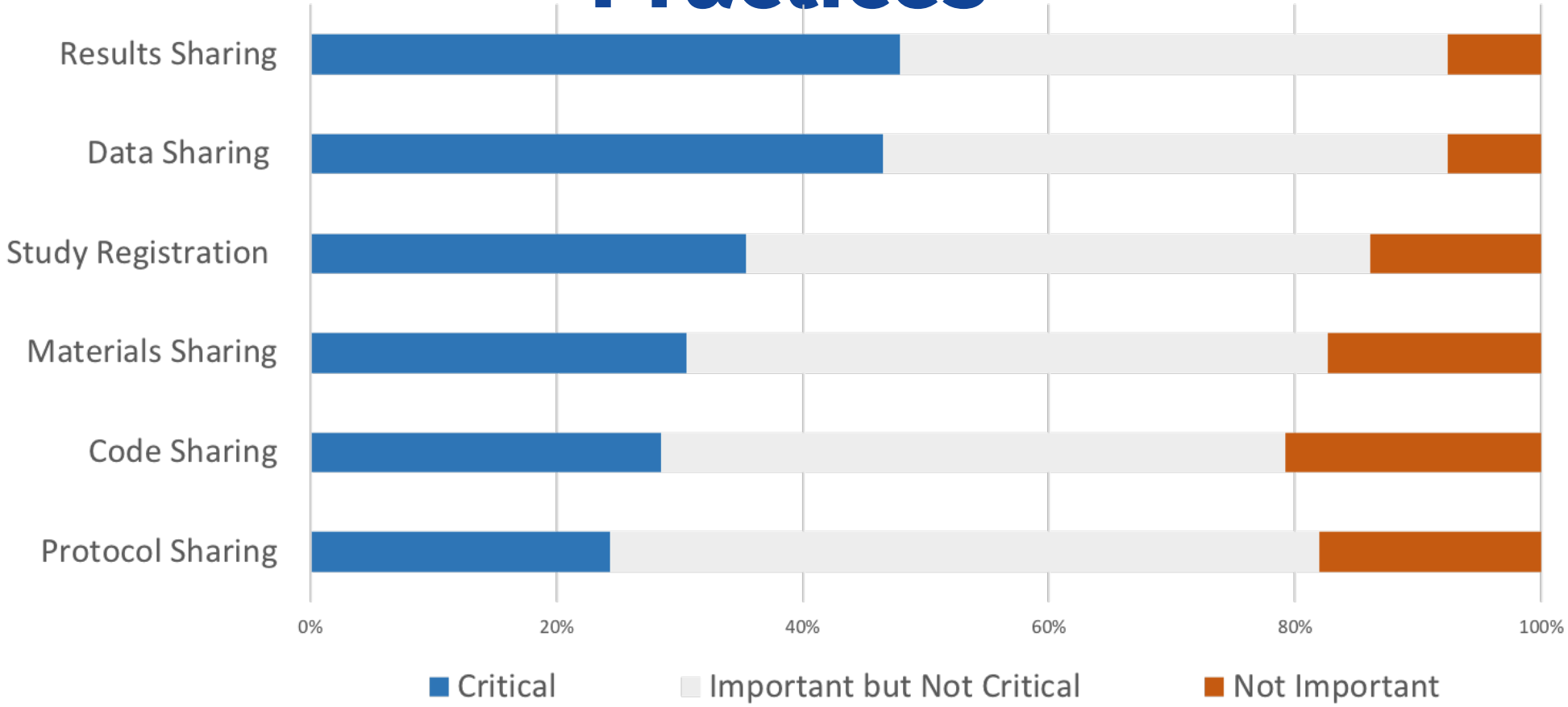
OHRP Guidance on Open Science Practices



AAHRPP Standards on Open Science Practices



PRIM&R Competencies on Open Science Practices



Implementation Considerations

Theoretical Domain	Consideration
Motivation: Role and Identity	More likely to engage with open science practices that fit their role/identity (as perceived by self and others)
Opportunity: Environmental Context	More likely to engage with open science practices if recommended by key organizations (OHRP)
Opportunity: Social Influences	More likely to engage with open science practices if supported by professional peers (other IRBs, faculty at their institution)
Capability: Beliefs about Capabilities	Stronger beliefs about the capabilities of other professionals at their university to check adequacy of open scientific practices (but they could potentially coordinate this review)

Potential Future Directions

- **OHRP to develop guidance on role of IRBs in open science**
  - Recommendations (for & against) policies and procedures
- **Universities to establish policy on role their IRB has (in the context of their institutional ecosystem)**
  - Engage multiple stakeholders at university, particularly faculty and other research offices
- **Design education and training enabled by the above**

References

- Doernberg & Wendler (2016). Ensuring respect for human research participants: institutional review boards and sharing results from research. JAMA, 316(11), 1149-1150.
- Grant & Bouskill (2019). Opinion: Why institutional review boards should have a role in the open science movement. Proceedings of the National Academy of Sciences, 116(43), 21336-21338.
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- Meyer (2018). Practical tips for ethical data sharing. Advances in Methods and Practices in Psychological Science, 1(1), 131-144.
- Michie et al. (2014). The behaviour change wheel. A guide to designing interventions. 1st ed. Great Britain: Silverback Publishing, 1003-1010.

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HRPPs and the Open Science Movement

Benjamin C. Silverman, M.D.
Senior IRB Chair, Mass General Brigham

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The Awesome Potential of Open Science: Two Case Examples

Human Genome Project

- Bermuda Principles (1996-1997)
  - Primary genomic sequence should be in the public domain
  - Primary genomic sequence should be rapidly released
    - Sequences greater than 1 Kb automatically released on a daily basis
    - Finished annotated sequences released immediately to public databases
  - Coordination of sequencing efforts
    - Notification of intentions to sequence certain regions of the genome
    - Made available online
  - Patents should not be sought
  - Funding agencies urged to foster these policies
  - Encourage research and maximize benefits to society

Maxson Jones K, Ankeny RA, Cook-Deegan R. J Hist Biol. 2018 Dec;51(4):693-805.

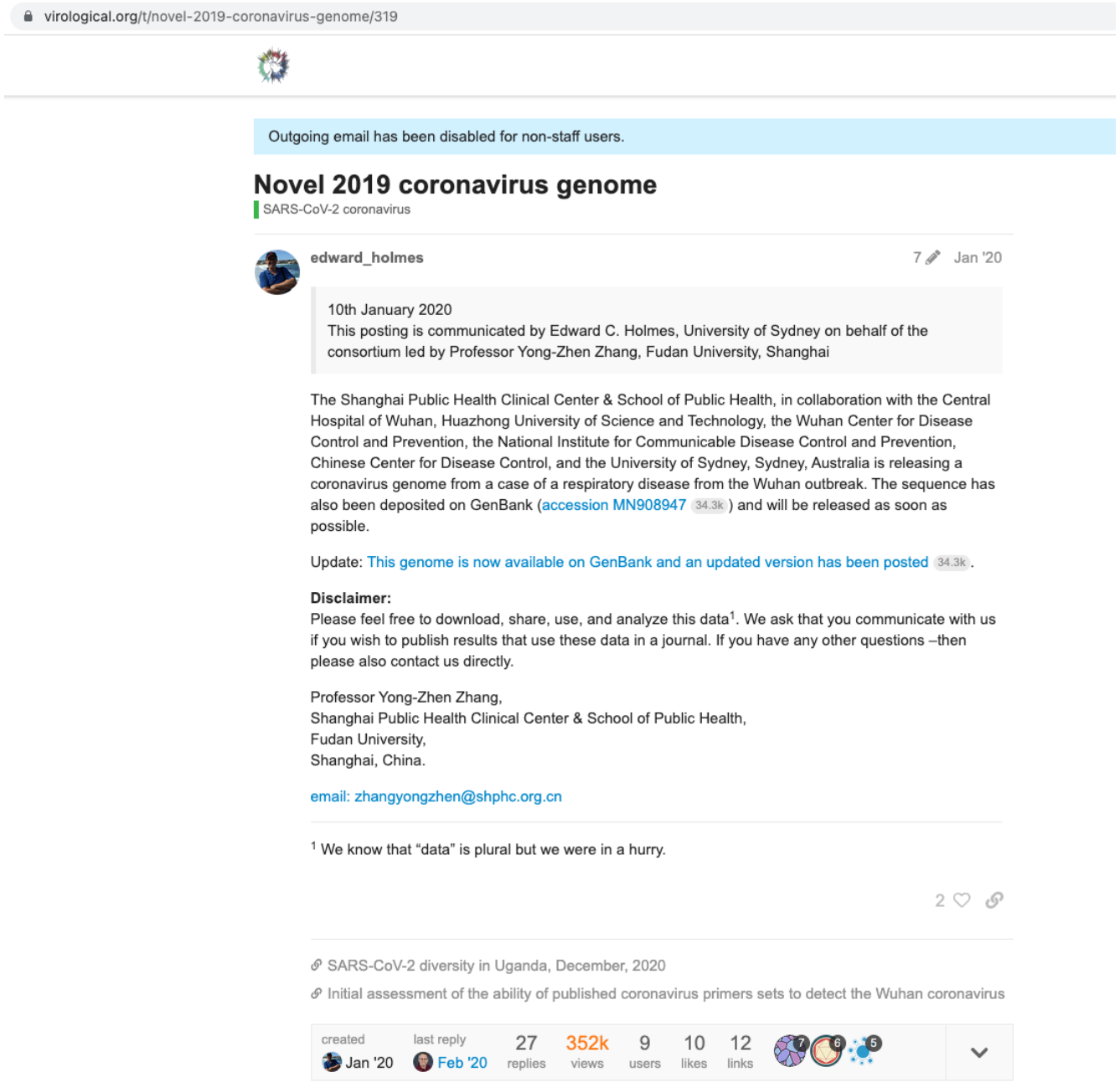
- Ahead of schedule and under budget
- Successful use of the public domain
- Open science is an enduring legacy of HGP

"They worked without resting and gave it away." –Francis Collins

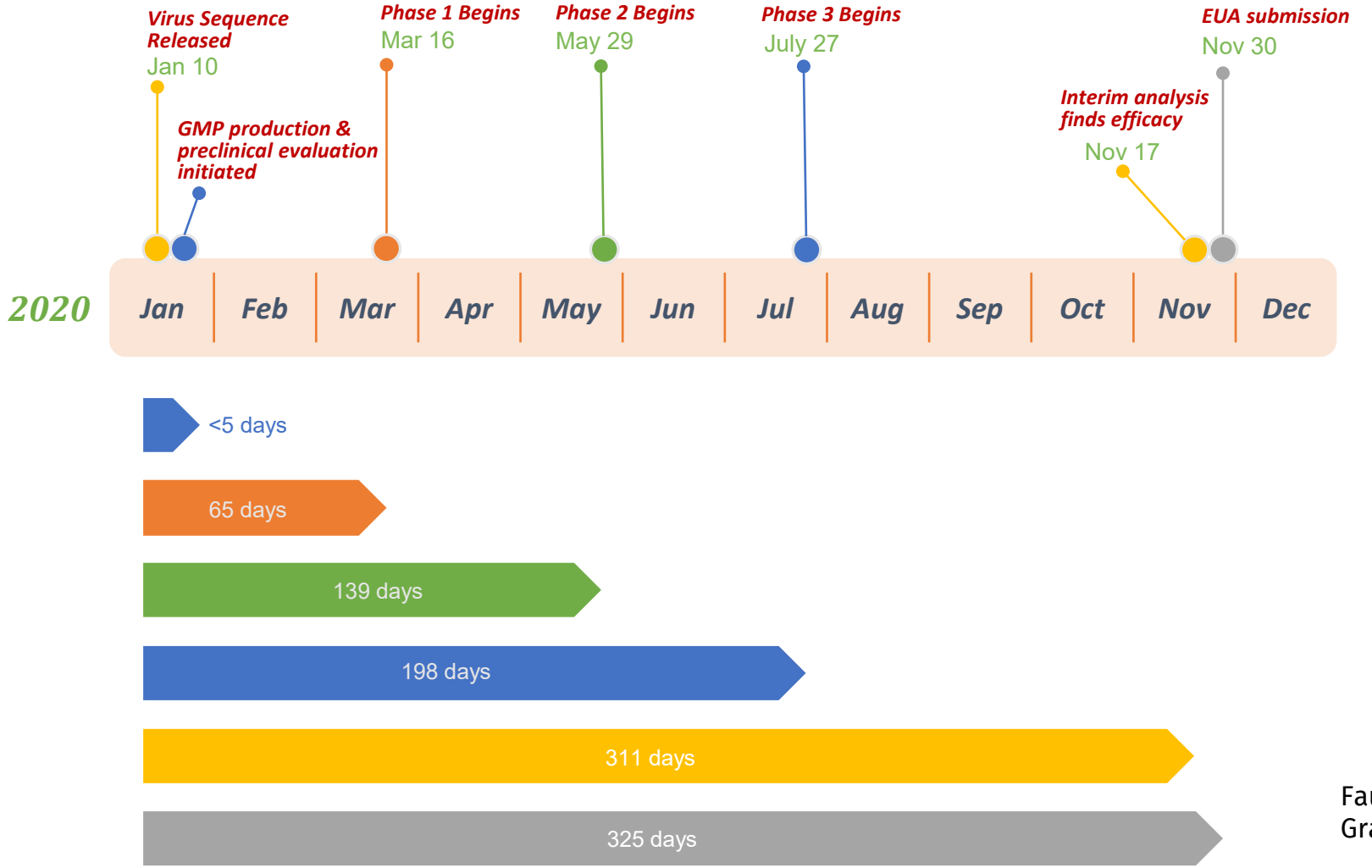
Jasanoff. Designs on Nature: Science and Democracy in Europe and the United States. 2005.

SARS-CoV-2 genome published online in public access database on January 10, 2020.

- Submitted to NCBI GenBank on January 5, 2020 and published January 12, 2020
- Published online in *Nature* on February 3, 2020
- Published in print in *Nature* on March 12, 2020



SARS-CoV-2 mRNA-1273 Vaccine Development



Fauci, Harvard Medical School Grand Rounds, 3/2/2023

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The Awesome Potential of Open Science… So, What's the Big Deal?

The Challenge of Open Science

- How much and what data do you have to have to share to accomplish the benefits of open science?

- At what point does that sharing infringe on other ethical obligations we have to our patients and research participants?

Benefits of Open Science

- Transparency
- Reproducibility and Accountability
- Collaboration
- Community Engagement

Benefits of Open Science

- Transparency → Trial and hypothesis registration
- Reproducibility and Accountability → Access to research protocols and scientific data sufficient to validate and replicate research findings
- Collaboration → Timely and open access to scientific data and results
- Community Engagement → Timely and understandable (i.e., plain language) access to results

- Better Science!

The Risks of Open Science

Risks to Rights of Patients/Participants or Groups:

- Breach of confidentiality/privacy
- Right to know what's done to your data and tissues
  - Especially if they are identifiable (including because human subjects research regulations still apply)

The Risks of Open Science

Risks to Scientific Integrity:

- Data problems
  - Unverified
  - Misuse
  - Tampering
- Intellectual property concerns

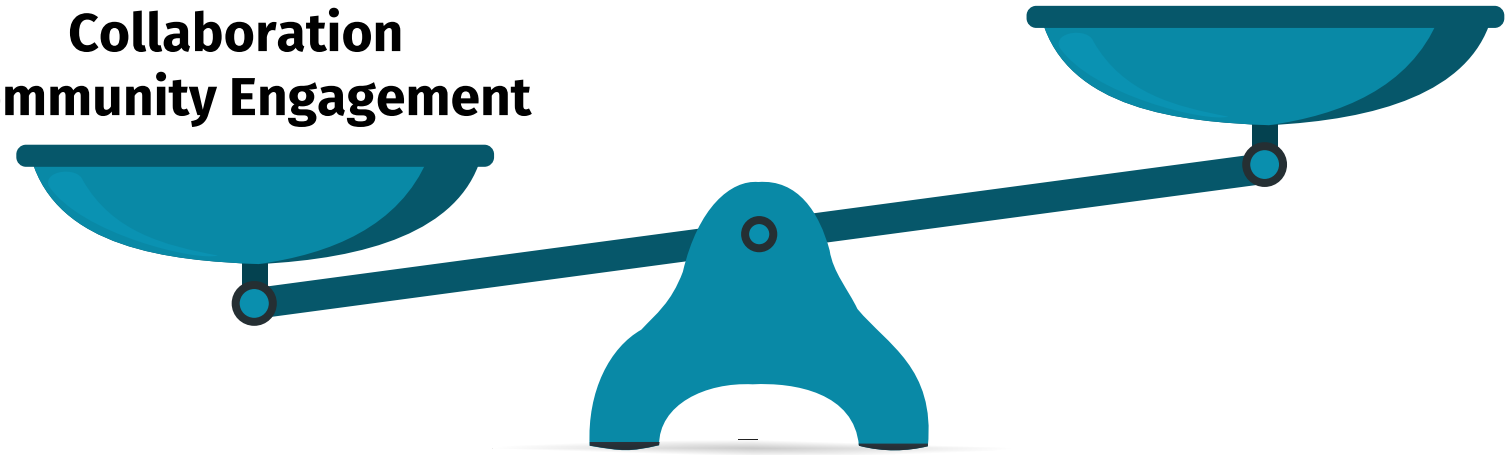
How Do We Achieve the Right Balance?

Benefits

Transparency
Reproducibility
Accountability
Collaboration
Community Engagement

Risks

Confidentiality/Privacy Risks
Autonomy Risks
Data Use Risks



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Case Example: 2023 NIH Data Management & Sharing Policy

2023 NIH Data Management & Sharing Policy

- The final DMS Policy does not create a uniform requirement to share all scientific data (NOT-OD-21-013).
- Appropriate data sharing is likely to be varied and contextual (NOT-OD-21-013).
- NIH expects that in drafting Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared (NOT-OD-21-013).
- NIH promotes the responsible sharing of scientific data consistent with protecting research participant privacy (NOT-OD-22-213).

What are the Ethical Limitations?

- Risk to privacy and confidentiality of participants
- Risk of harm to individual subjects or groups/populations
- Risk of violating other laws or regulations

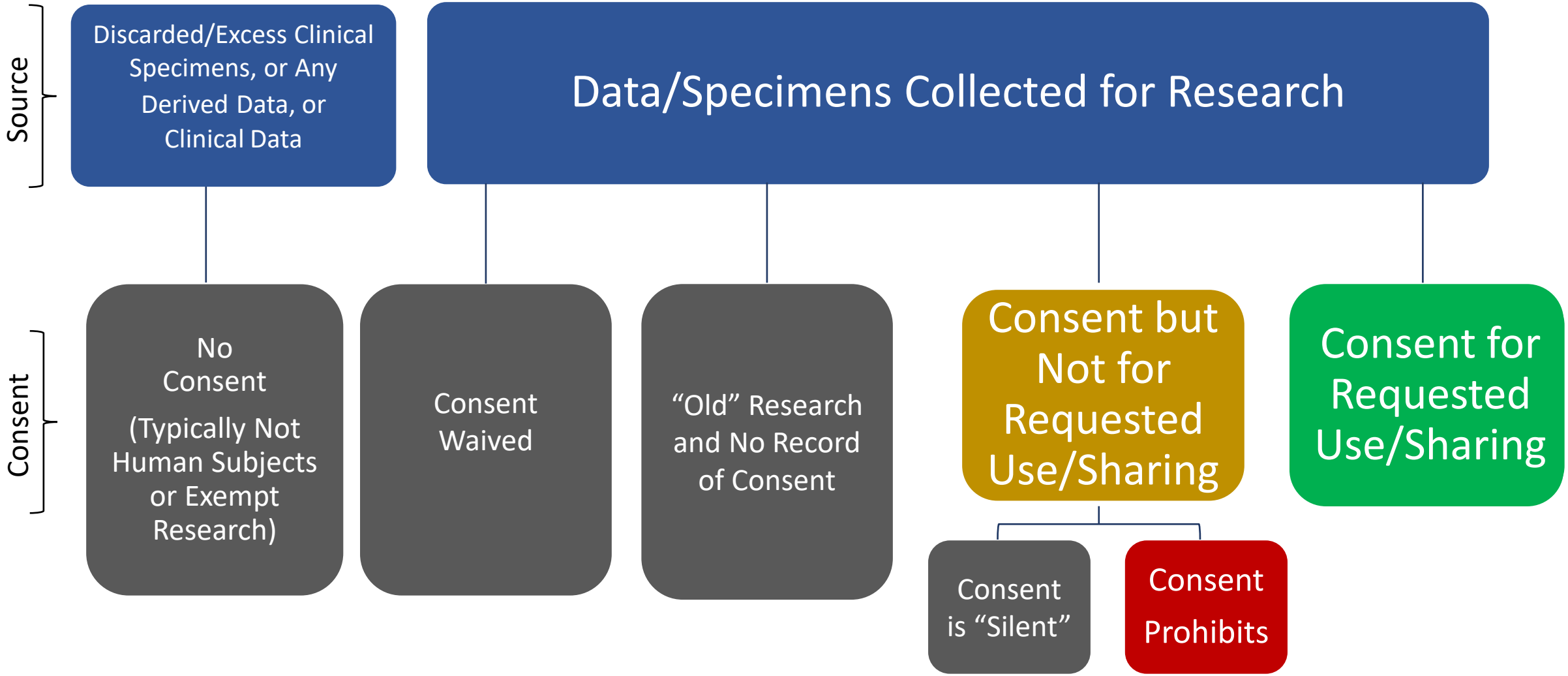
How Can You Minimize Privacy Risks?

- Place limits on data sharing
  - When the data might compromise privacy or safety of participants
  - Sensitive data (e.g., stigmatizing, illegal behaviors, potential for group harm)
  - Limitations could be imposed by institutions, HRPPs, and/or IRBs
- Apply de-identification when possible (acknowledging its limits)
- Share through controlled access databases
- Establish data sharing and use agreements
  - DUA terms may also protect against data misuse
  - Ensure consistency of agreements with consent
- Apply privacy protections regardless of data type (e.g., NHSR)
- Appreciate other protections that may apply (federal, tribal, state, and local laws, regulations, and policies, for example, CoCs)

How Can You Minimize Individual or Group Risks?

- Ensure consent for the data sharing and future use has been obtained
  - With as much specificity as possible, include where and with whom data will be shared (e.g. controlled or open access repositories, collaborators or non-collaborators, non-profit or industry, etc), and any restrictions or limitations on sharing and future use (e.g., disease specific, type of analyses, etc).
  - IRBs have a required role in approving consents with this intended sharing
  - Institutions and HRPPs could be involved in implementation of data sharing policies and broad consent plans and reviewing agreements and sharing plans.
- Obtaining consent for future research use of data (and samples) upholds respect for persons, their values, and their autonomous choices, minimizes privacy risks, and promotes public confidence in medicine and research.

Source of Data and Participant Consent



Which Human Data May be Shared?

- Any limitations or restrictions described in the Informed Consent Document/Process must be honored
  - Type of sharing: Controlled access, uncontrolled/public, etc.
  - Data Use limitations: specific users, specific conditions/diseases
  - Destruction dates
- Any federal, state, local, or Tribal law, regulation, or policy that prohibits disclosure must be honored
- Any restrictions or limitations of current or anticipated agreements must be honored

Which Human Data May Not be Shared?

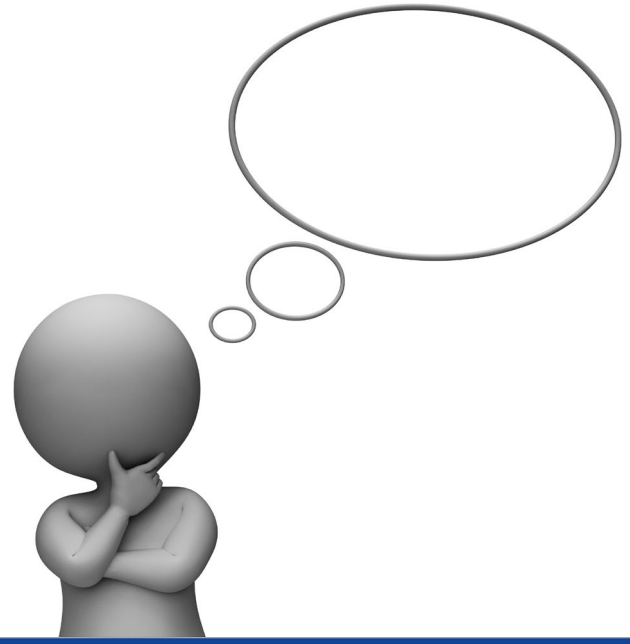
- Individual-level clinical/electronic medical record notes even if considered de-identified.
- Data with small cell sizes or data that can be used to infer information about or inadvertently identify an individual
- Data that may be harmful or stigmatizing to an individual or to a particular group of people or a population.
- Any other individual-level “sensitive” data.
  - The NIH describes “sensitive” as “…including information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes. Sensitive data may also include data from individuals, groups, or populations with unique attributes that increase the risk of re-identification.” (NOT-OD-22-213)

How Should Human Data Be Shared?

- Data must be anonymized or de-identified under HIPAA standards and requirements of federal human subjects regulations.
- Data may only be shared in controlled access repositories/conditions
  - EXCEPTION: Only data collected with explicit human research consent as approved by an IRB for sharing in public/open-access repositories may be shared in public/open access conditions.
  - Research subject to the GDS policy must also follow the funding-specific requirements for sharing and data use limitations (DULs).

How Can We Incentivize Open Science?

- IRBs/HRPPs tend to be conservative and prioritize protection of and risk minimization to participants.
- Researchers tend to be protective of their work and intellectual property.
- No one needs extra work.
- Regulatory changes will create requirements.
- Education and community engagement are essential.
- Consent is really *the answer*.



Take Home Points

- Open science has the awesome potential to lead to better science.
- HRPPs/IRBs play a critical role in maximizing the benefits and minimizing the risks of open science.
- HRPPs/IRBs should develop policies that both facilitate open science and protect participant autonomy and privacy.
  - Institutional policies on open science data sharing: What is required, encouraged, permissible, and restricted?
  - Procedures to ask researchers about data sharing and future use plans at the time of research initiation (and procedures for what to do if those plans change).
  - Templated consent form language to address different types of data sharing and future use.
- The best protection of autonomy and privacy in open science will require implementation of more transparent “permission” (or broad consent) for sharing and future use of clinical and research data and samples.

Acknowledgements

Martha Jones

Post-Presentation Poll

- Now that you have heard the discussion, do you think consideration of open science practices falls within an IRB's responsibilities?
  - Yes
  - No
  - Unsure

Post-Presentation Poll

- Do you think IRBs should actively support open science practices?
  - Yes
  - No
  - Unsure

Questions?

Thank You!