Research Integrity Reform: Two Roles for Research Ethics

Michelle N. Meyer, PhD, JD

Chair and Associate Professor
Department of Bioethics and Decision Sciences
Geisinger College of Health Sciences

Chief Bioethics Officer, Geisinger Health System

Geisinger College of Health Sciences

Two Roles for Research Ethics

1. Human Research Protection Programs (HRPPs) should actively promote and facilitate open science practices as an inextricable part of research participant protection.
2. Research ethics should balance this open science imperative against the risks and inequities it sometimes imposes.

U.S. “Common Rule” 45 C.F.R. § 46.111(a)

“In order to approve research . . . the IRB shall determine that . . . :

- Risks to subjects are reasonable in relation to . . . **the importance of the knowledge** that may reasonably be expected to result.”

- Risks to subjects are minimized . . . [b]y using procedures that are consistent with **sound research design** . . .

Association for Accreditation of Human Research Protection Programs (AAHRPP)

- “The organization has and follows written policies and procedures for reviewing the scientific or scholarly **validity** of a proposed research study.” (Element I.1.F)
- “Researchers should **design research** studies so that the research will most likely develop or contribute to generalizable **knowledge**.” (Element III.1.C)
- “Researchers should have the resources required to conduct research in a way that will protect the rights and welfare of participants and ensure the **integrity of the research**.” (Element III.1.D)

HHS Secretary's Advisory Committee on Human Research (SACHRP), 2003–2025

Studies must not be foreseeably **uninformative.**

They must:

(1) address a socially important question and

(2) be **validly designed** to do so.

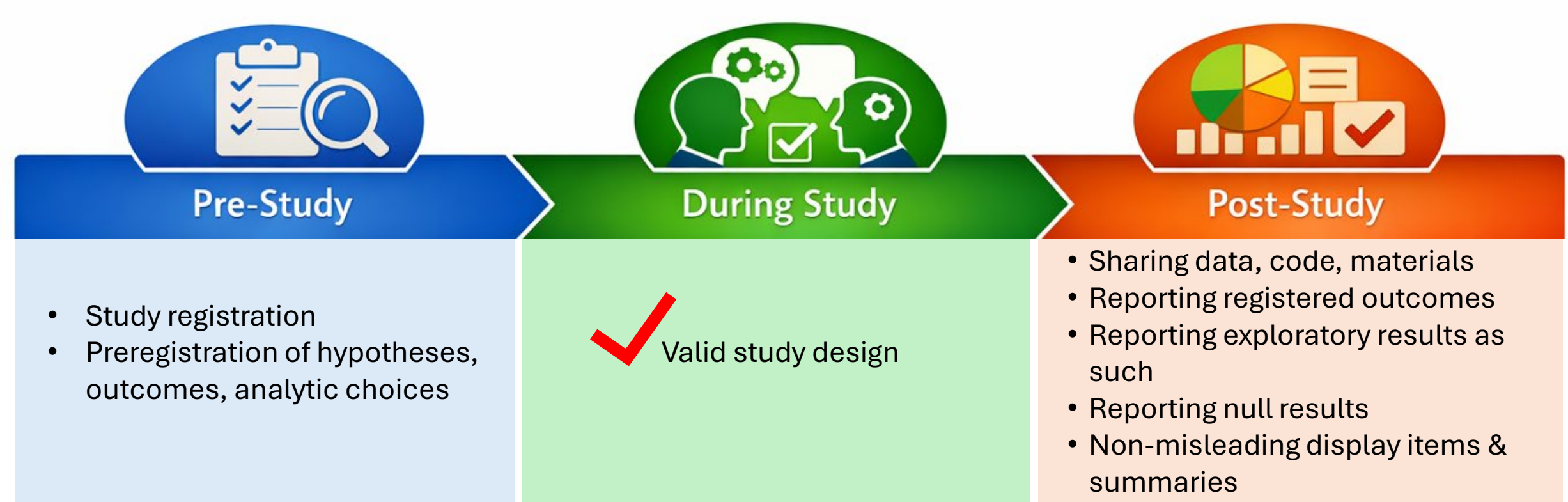
Red flags for IRBs: flawed methodology, lack of expertise, unappreciated resource limitations, patterns of failure to meet enrollment targets, closed RQs

"Assessment Considerations for Uninformative Research," October 22, 2024

Research Results Alone ≠ Knowledge

Research Results Alone ≠ Knowledge

- The same logic that supports an ethical requirement of a **valid study design** extends to **all choices** across the research lifecycle that affect a study's ability to contribute to knowledge.
- To justify risks and burdens to participants, research must (1) address an important question, (2) be validly designed to answer it, and ***(3) be verifiable and credible***.
- Research integrity is the *responsibility* of the researcher, but other parties can serve as facilitators, incentivizers, and accountability partners.



One example: data sharing

— Across the social and behavioral sciences, the data are not available upon request:

Wolins, 1962 (psychology)
Craig & Reese, 1973 (psychology)
Wicherts et al., 2006 (psychology)
Vanpaemel et al., 2015 (psychology)
Hardwicke & Ioannidis, 2018 (psychology & psychiatry)
Zenk-Möltgen et al., 2018 (sociology & political science)

— Lack of participant consent or IRB approval for data sharing often cited as a barrier:

Washburn et al., 2018 (psychology)
Hardwicke & Ioannidis, 2018 (psychology & psychiatry)
Tedersoo et al., 2021 (cross-disciplinary)
Gabelica et al., 2022 (biomedical)

One example: data sharing

— (Most) IRBs are not *opposed* to data sharing. What if they embraced it as a necessary part of risk/knowledge balance and were active *proponents*?

— *Very unscientific* review of online IRB consent templates (collaboration with Claude Opus)

- Some say nothing about data sharing or, worse, promise "confidentiality," making subsequent sharing a questionable choice.
- Many offer multiple options, from no sharing outside the study team to open sharing, but make none the default and offer no guidance about how to choose. Researchers may worry that IRB approval or recruitment will be harder/slower with data sharing.
    - In fact, some evidence that participants support data sharing and even assume it's already occurring: Mello et al., 2018 (clinical trials); Mozersky et al., 2020 (qual); Bottesini et al., 2022 (minimal risk studies with university students or online crowdworkers)
- Only one observed consent template (Geisinger's, at my urging) provides multiple options, but nudges researchers towards sharing by noting that "broad sharing…should be the default option" and is often required by sponsors and journals.
- None *make* sharing the default by requiring researchers to justify a decision *not* to share.

When research ethics cuts the other way…

— Sometimes it *is* ethically problematic to share data.

- It's possible to reidentify individuals from a wide range of data (e.g., health survey responses, search queries, geolocation, social network structure, movie reviews).
- *But* ethics should not be reflexively cited as a reason for not sharing
- Lots of strategies for addressing privacy risk even with sensitive data (Meyer, *AMPPS* 2018), e.g., restricted/controlled access repositories; privacy-preserving techniques

— Well-intended reforms can have disparate impacts on different researchers/research institutions.

- E.g., not all researchers have access to de-identification services
- A more equitable solution might be for sponsors and journals to provide de-identification services

Conclusions

— HRPPs/IRBs already explicitly balance participant risks and burdens with the expected value of the knowledge produced

— They therefore rightly have a role in helping to ensure valid study design and—by the same logic, compliance with a range of open science practices designed to ensure verifiability and credibility

— Open science practices themselves can raise ethical issues that must be included in the moral calculus

—HRPPs/IRBs aren’t the only or most important player in open science reform, but for this large of a problem, we need all players in the research ecosystem to step up