Open Science and Institutional Review Boards: Aligning Research Transparency with Regulatory Protections for Human Research Subjects

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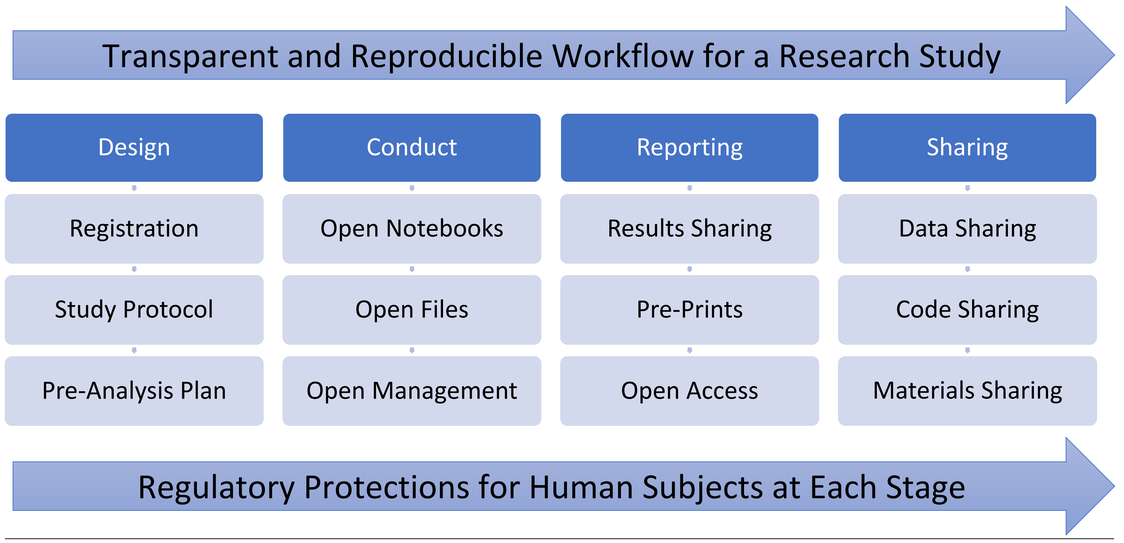
Background

- The research enterprise is shifting toward a model of "open science" by design
- "Open science" aims to ensure the free availability and usability of scientific research processes and outputs
- Numerous stakeholders are responding to these changes in the research enterprise
- Institutional review boards (IRBs) are a key stakeholder group that may need to adapt as open science practices become the norm in human subjects research

Open Sciences Practices



Office of Human Research Protections

- OHRP's responsibility "to ensure that DHHS human subjects protection regulations are appropriately and effectively applied <u>to the changing needs of the research community</u>"
  - "Open science by design" as changing need
- We are still awaiting guidance on
  - Technologies/techniques that could make data identifiable
  - Adequate provisions to protect subject privacy and maintain data confidentiality

Methods

- To facilitate conversation on the role of IRBs in a research enterprise that is "open by design", we conducted the following:
  - document analysis of federal regulations, policy, and guidance that apply to the protection of human subjects in health research
  - survey of 132 IRB chairs and administrators at R1 or R2 universities
  - interviews with 33 IRB chairs and administrators at R1 or R2 universities
- We examined how to align IRBs with open science practices (see figure) while remaining sensitive to the IRB regulatory environment

Belmont Report

- <u>Respect for persons</u> as a basis for subjects providing informed consent about what will (not) happen to their data
- <u>Beneficence</u> as a basis for requiring that research has a favorable risk/benefit ratio
  - Risk: Open sharing leading to privacy/confidentiality breach
  - Benefit: Knowledge gained
- <u>Justice</u> as a basis for research benefiting the public
  - Also a key goal of the movement to open science

45 CFR 46

- Sharing data (and possibly code/materials) influences
  - Research activity as involving human subjects
  - Exemption and expedited, limited, and continuing review
  - Informed consent
- Reporting and sharing could be considered part of "generalizable knowledge" for IRB approval
- Broad consent as new mechanism for sharing
- IRBs can approach expert consultants in data sharing

Recommendations

- Study proposal forms/systems could include specific fields for each open science practice
- IRBs should create written guidance explaining how open science practices can escalate the level of IRB review and potentially prevent IRB approval
- IRBs should provide templates of informed and broad consent forms with approved language on data, code, and materials sharing
- IRBs can invite open science experts as members or to assist on a case-by-case basis
- Open science proponents should solicit OHRP to create guidance on IRB policies and procedures that enable transparent yet compliant human subjects research

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