
Sean Grant, Indiana University Fairbanks School of Public Health
Kathryn Bouskill, RAND Corporation

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

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

Open Sciences Practices
- Transparent and Reproducible Workflow for a Research Study
- Design
  - Registration
  - Study Protocol
  - Pre-Analysis Plan
- Conduct
  - Open Notebooks
  - Open Files
  - Open Management
- Reporting
  - Results Sharing
  - Pre-Prints
  - Open Access
- Sharing
  - Data Sharing
  - Code Sharing
  - Materials Sharing

Regulatory Protections for Human Subjects at Each Stage

Office of Human Research Protections
- OHRP’s responsibility “to ensure that DHHS human subjects protection regulations are appropriately and effectively applied to the changing needs of the research community”
- “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

Belmont Report
- Respect for persons as a basis for subjects providing informed consent about what will (not) happen to their data
- Beneficence as a basis for requiring that research has a favorable risk/benefit ratio
  - Risk: Open sharing leading to privacy/confidentiality breach
  - Benefit: Knowledge gained
- Justice 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

This project is supported by the Robert Wood Johnson Foundation (Grant Number 74420) | Email: spgrant@iu.edu | Twitter: @GrantSeanP