

# Institutional Review Boards

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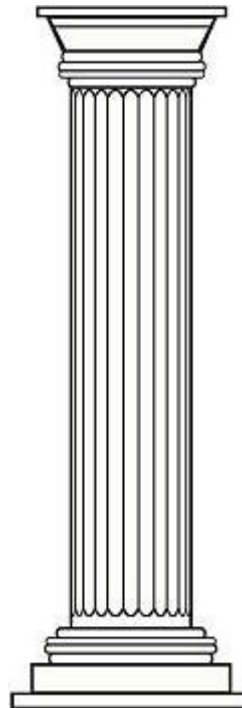
# Disclaimer

The views expressed in this talk are mine.  
They do not represent the position or policy  
of the NIH, DHHS, or US government

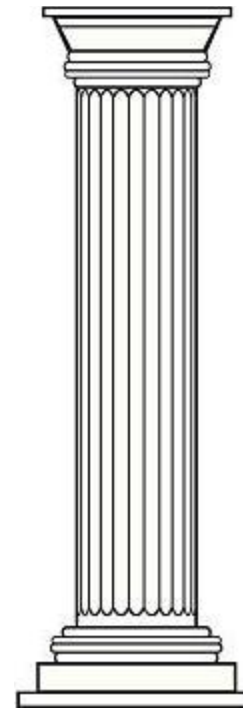
# Key Points

Two pillars in  
protection of  
human subjects

Institutional  
Review Board



Informed  
Consent



# Key Points

- Institutional Review Boards (IRBs) are responsible for the review and oversight of human subject research
  - In other countries the group in charge of the review and oversight of research is called a:
    - Ethical Review Board
    - Independent Ethics Committee
    - Research Ethics Committee
    - Research Ethics Board

# Key Points

- IRBs in the US are guided in their review by Federal Regulations
  - HHS: 46 CFR 46
  - FDA: 21 CFR 56
- IRBs in the US are LOCAL, they develop their own policy and practice based on Federal Regulations
  - Outside of the US they can be regional or national

When in doubt,  
ASK

# Ethical Requirements: Independent Review

- Review of research (design, population, risk/benefit) by unaffiliated individuals to:
  - Assure public/social accountability
  - Minimize impact of potential researcher COI

Emanuel *et al* (2000) *JAMA*

# Transformative Effects of IRBs

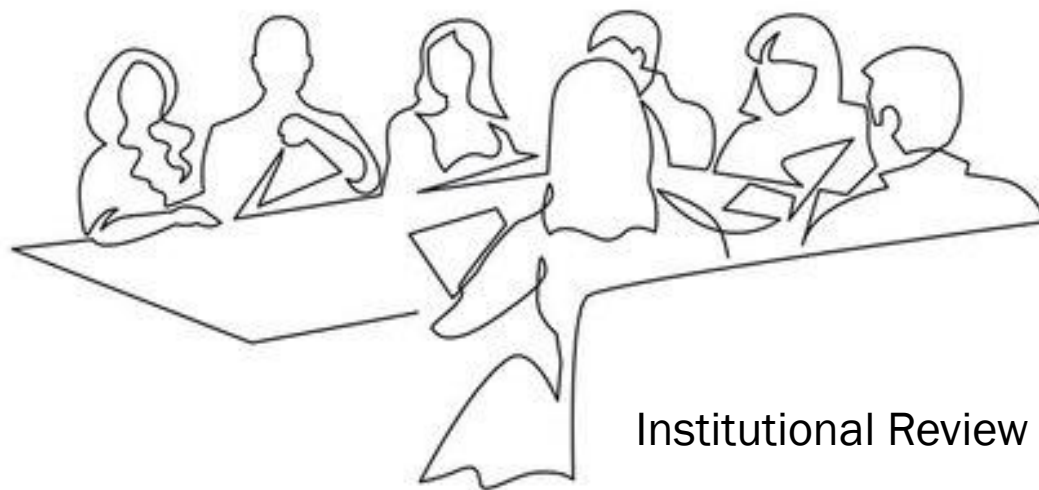
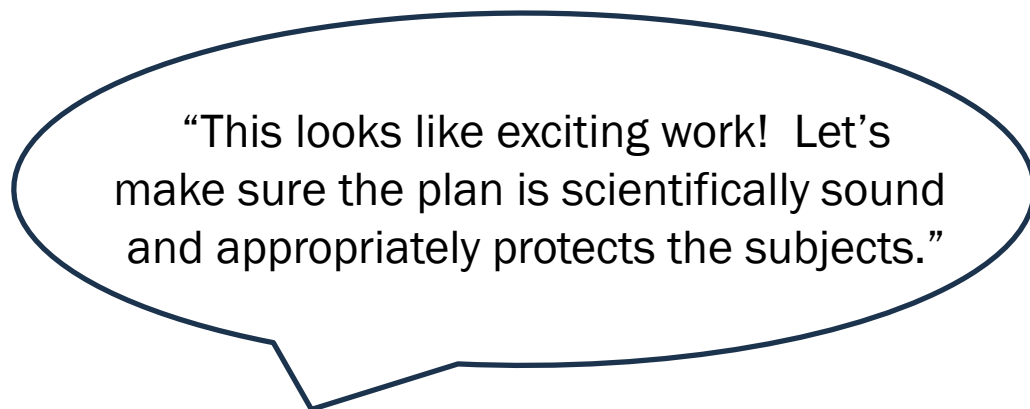
- “Unquestionably, their very existence has tempered the inevitable propensity of researchers to pursue investigations without dispassionately weighing the risks they are asking others to assume or fully informing their subjects of them.”

Edgar and Rothman (1995) *Milbank Q*

# Conflict of Interest



Investigator



Institutional Review Board



# Overview

- Role
- Scope
- Responsibilities
- Review

# Role

- Review and Oversight
  - Component of Human Research Protection Program
- IRB membership in US
  - Need minimum of 5 members
  - Local, autonomous committee
    - Variability in review

# Role

- Challenges
  - Conflict of Interest
    - Individual
    - Institutional
  - Group dynamics
    - Observer drift
    - Groupthink

# Scope

- Necessity of IRB
  - Need review to get Federal funds (e.g. NIH grant)
  - Other funders require ethics review (e.g. Gates)
  - FDA requires IRB review

# Scope

- Federal Wide Assurance
  - Mechanism by which IRB **assures** Federal government that it will review research according to 45 CFR 46
    - Review regardless of funding mechanism
    - Follow principles of Belmont (US)
    - Follow internationally recognized standard (Non-US)

# Responsibilities

- Review Criteria (46 CFR § 46.111)
  - 1) Risks minimized
  - 2) Risks reasonable when compared with anticipated benefit
  - 3) Selection of subjects equitable

# Responsibilities

- Review Criteria (46 CFR § 46.111)
  - 4) Informed consent will be sought
  - 5) Informed consent will be documented
  - 6) Safety monitoring provisions
  - 7) Special protections for vulnerable subjects

# Responsibilities

- Additional Criteria
  - Local Institution/IRB Policy
  - NIH Guidelines
  - FDA Regulations
  - State Law
  - Other recommendations



# Review of “Research”

- “Research: A systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge.”

45 CFR § 46.102 (e)

# Review

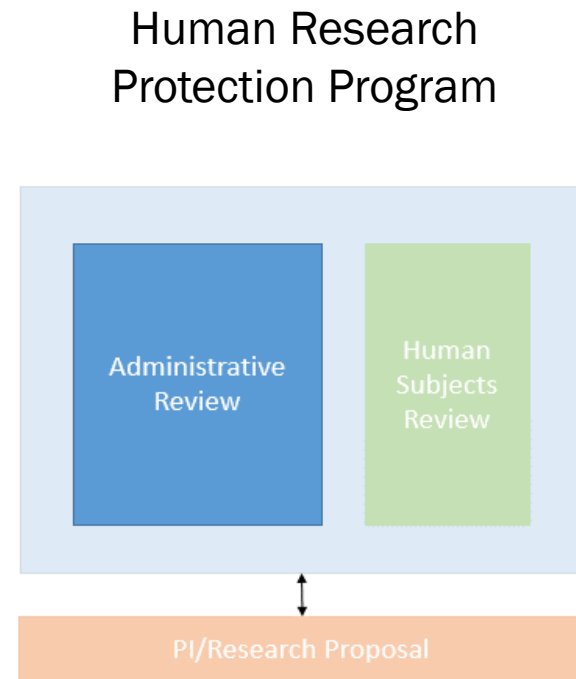
- Categories of Research
  - Not Human Subject Research
  - Exempt from IRB Review
    - No more than minimal risk
    - Meets one of 8 criteria (e.g. Data collection without identifiers)

# Review

- Categories of Research
  - Expedited Review
    - No more than minimal risk
    - Can be reviewed by Chairperson or experienced reviewer
  - Full Committee Review
    - More than minimal risk

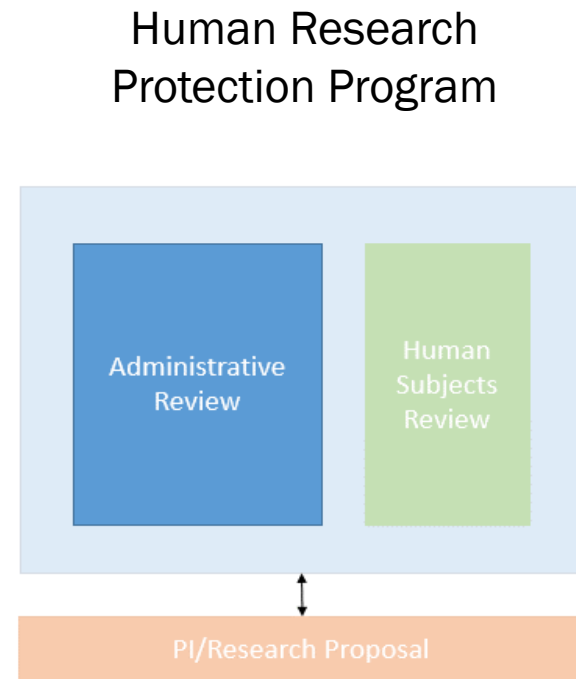
# Review Process

- Initial Administrative Review
  - Research plan
  - Consent documents
  - Advertisements
  - Coordination of other ancillary reviews



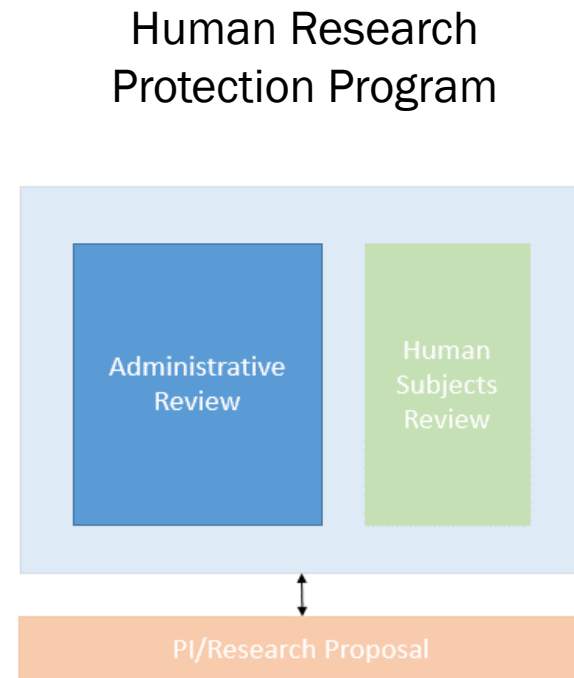
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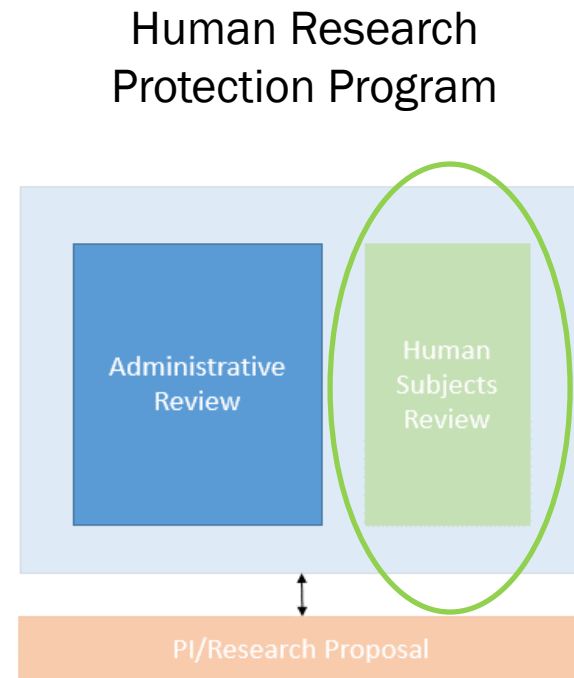
# Review Process

- Deliberation
- Decision
  - Approve
  - Approve with stipulations
  - Defer
  - Disapprove



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# Review Process

- Continuing Review
  - Annual updates
    - For protocols reviewed by Full Committee
  - Amendments to study
  - Adverse event reports



# Single IRB of Record

## SUBPART A OF 45 CFR PART 46: BASIC HHS POLICY FOR PROTECTION OF HUMAN SUBJECTS

As revised January 19, 2017, and amended  
on January 22, 2018 and June 19, 2018

US Department of Health and Human Services

### §46.114 Cooperative research.

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

## Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Notice Number: NOT-OD-16-094

### Key Dates

Release Date: June 21, 2016

Effective Date: New Date - January 25, 2018 as per issuance of NOT-OD-17-076

### Purpose

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy, which is consistent with 45 CFR Part 46.114, is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

### Scope and Applicability

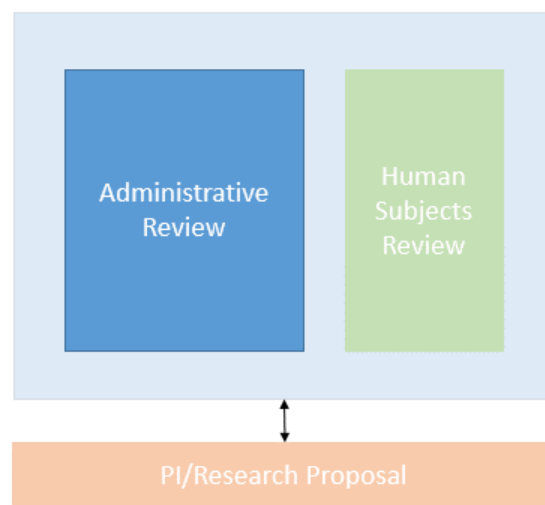
This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

Consistent with the Roles and Responsibilities section, applicants/offers will be expected to include a plan for the use of an sIRB in the applications/proposals they submit to the NIH. The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award or in the Contract Award. This policy also applies to the NIH Intramural Research Program.

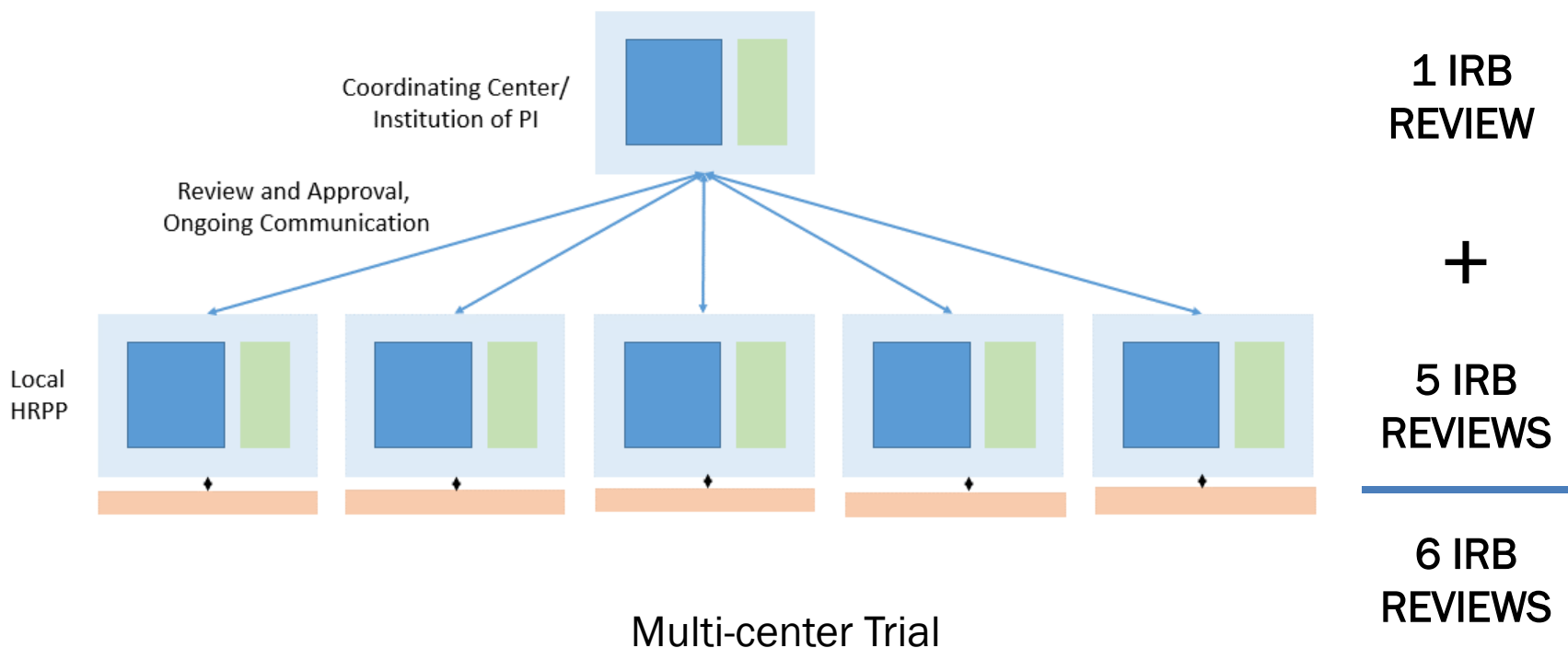
# Single IRB of Record

Human Research  
Protection Program



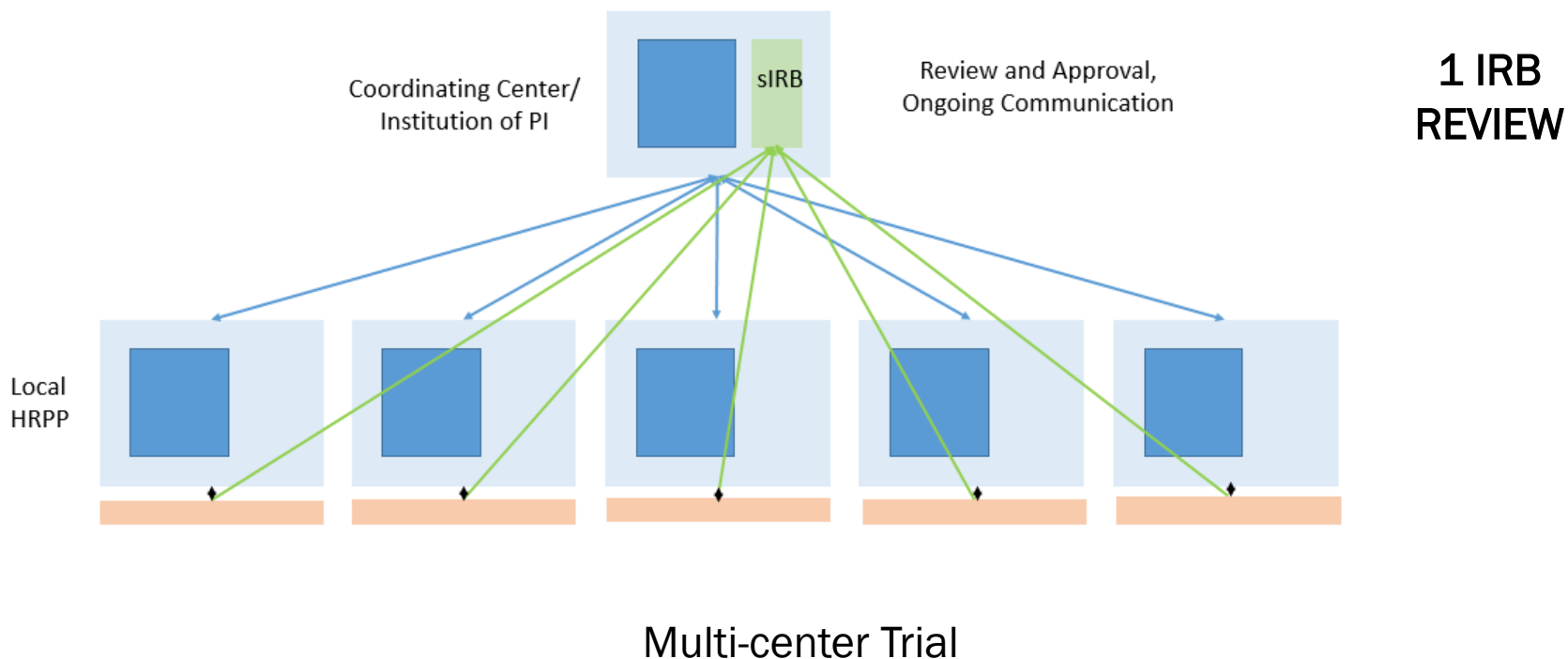
# Single IRB of Record

## Before sIRB Policy



# Single IRB of Record

## After sIRB Policy



# Single IRB of Record

- Evaluations
  - Underway
- Outcomes
  - Unclear
- Policy and Practice



<https://smartirb.org/>

# Summary

When in doubt,

ask your local  
committee!