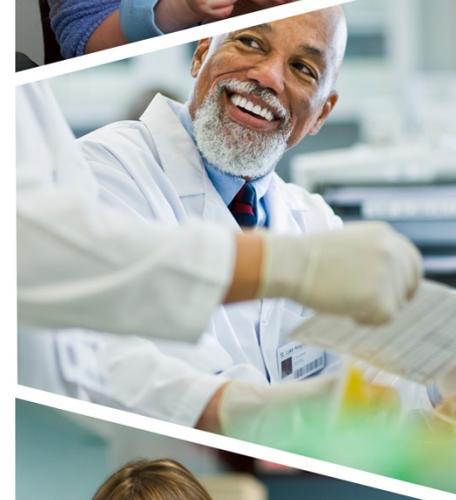


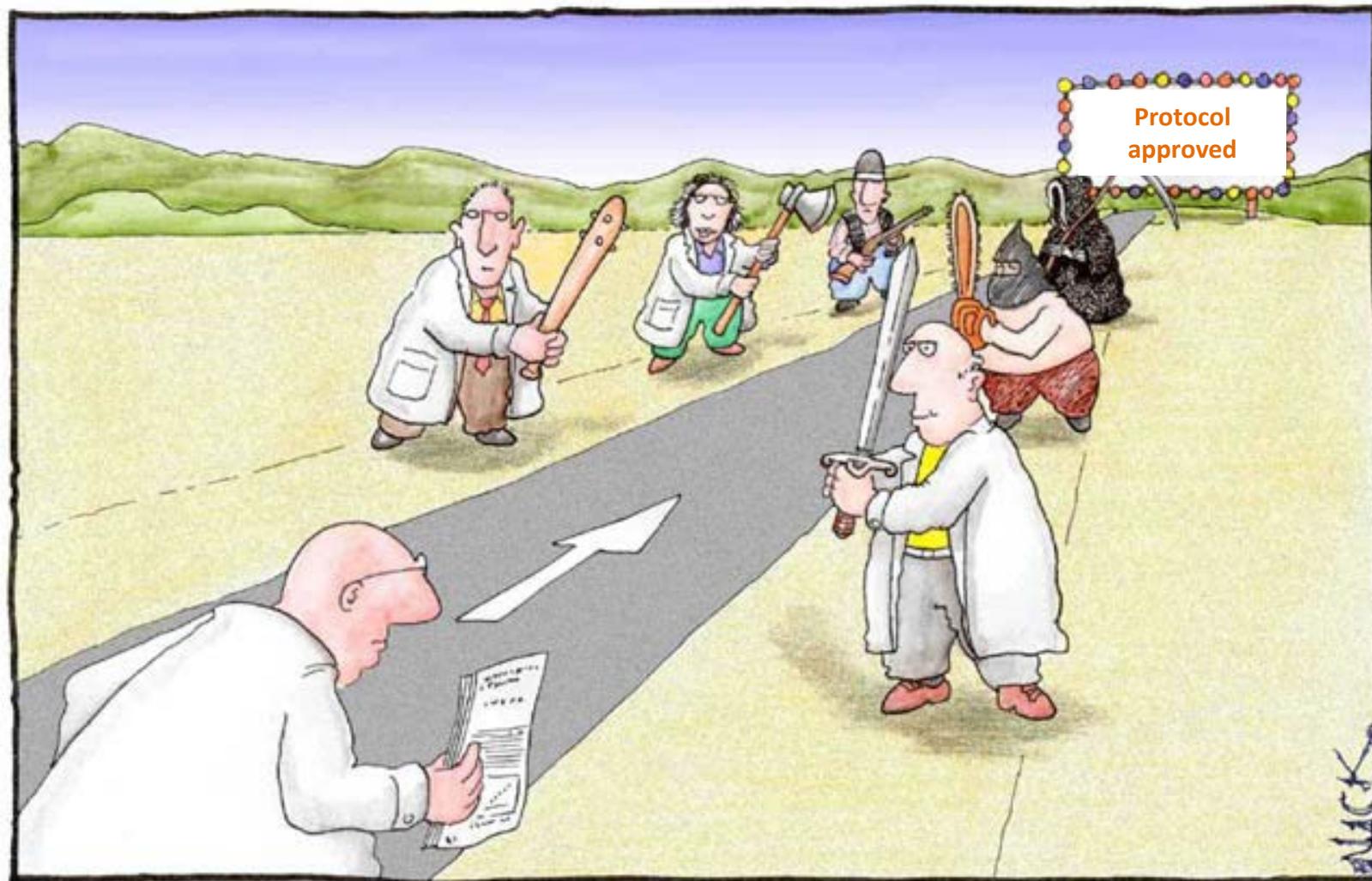
# NIH Policy Preview: Use of a Single IRB for Multi-Site Research

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# Multi-site IRB Review: There has GOT to be a better way



# Why a Single IRB Policy?

- Multiple IRB review does not appear to enhance the protection of participants
- Single IRBs reduce costs and review time
  - Better for science!
- Consistent with Common Rule reform proposing to mandate use single IRBs for multi-site studies
- Implements recommendation of the NIH Clinical Trials Working Group
- Concept has been tested by NIH and others

# Draft NIH Policy Released for Public Comment

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

### Notice Number:

NOT-OD-15-026

### Key Dates

**Release Date:** December 3, 2014

Related Announcements

**Response Date:** January 29, 2015

None

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

The National Institutes of Health (NIH) is seeking public comments on a draft policy to promote the use of a single Institutional Review Board of record for domestic sites of multi-site studies funded by the NIH.

### Background

The NIH is dedicated to improving the health of Americans by conducting and funding biomedical research through an extensive portfolio of human subjects research. While NIH-funded investigators must adhere to regulations for the protection of human subjects, the agency also looks for ways to reduce procedural inefficiencies so that human subjects research can proceed efficiently without....

# Elements of Proposed NIH Policy

- NIH-funded domestic multi-site studies supported via grants, contracts, or NIH IRP, will be expected to use a single IRB
- Single IRB will be accountable for compliance with 45 CFR 46 requirements for IRBs
- Single IRB will be identified by the applicant, offeror or intramural PI; IC will have final approval.
- Costs of fee-based IRB review will be included in the award as a direct cost.
- Exceptions allowed if:
  - Designated IRB unable to meet the needs of specific institutions or populations; or
  - Local IRB review is required by federal, tribal, or state laws or regulations.

# Who we heard from...

- Patient Advocates
  - Research Associates
  - Researchers/Research Organizations
  - IRB members/IRBs
  - Public
  - AI/AN Tribal Representatives
  - Healthcare Organizations
  - Professional Trade Organizations
  - Government Advisory Boards
- 

# What we heard...

- 70% Supporting Comments
  - Researchers, Research Associations, Patient Advocates, Tribal Representatives
- 30% Opposing Comments
  - IRBs/IRB members, Tribal Representatives, Research Organizations

# What supporters said...

- Separate IRB reviews increase administrative burden and time it takes to get a study launched
- sIRB will encourage:
  - more consistent adherence to protocols;
  - use of standardized protocols, resulting in more rigorous/valid study results;
- Multiple IRB review is duplicative
- Local IRBs focus on risk and liability (i.e., institutional interests) more than participant protections
- Changes required by local IRB changes are often trivial, they do not change nature or risk/benefit ratio of study, are often focused on the informed consent language

# Opposing views...

- sIRB use should be voluntary, not mandatory
- sIRB review appropriate under “certain circumstances,” such as national trials providing a single treatment
- Lack of evidence
  - to support need for policy
  - for benefit of sIRBs
- Lack of existing guidance related to roles & responsibilities of IRBs participating in the study

# What we specifically heard from Tribal Representatives

- Support for the exemptions for tribal law and/or specific population needs
- Comments available on OSP website:  
<http://osp.od.nih.gov/sites/default/files/resources/sIRB%2007-21-2015.pdf>

# What happens next?

- Final policy expected May 2016
- Will likely not go into effect until January 2017 for new and competing awards
- Developing implementation plans and guidance for NIH and extramural community

# Keep in Touch!



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