Should We or Shouldn't We: The Decision to Create a Scientific Review Committee

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Scientific Review Committee

Robert D Sege, MD PhD, Chair	(NEMC*)
Jerry Dallal, PhD	(Tufts*)
Patricia Hibberd, MD PhD	(NEMC*)
John Griffith, Ph.D	(NEMC*)
Susan Parsons, MD, MRP	(NEMC*)
Ex officio – IRB Chair,	(NEMC*)
Director of Research Integrity	(NEMC/Tufts)

* = Indicates the members primary appointments.

SRC Composition

- Chairman, an MD
- 4 additional committee members
- 2 MD's or MD/Ph.Ds
- 2 Ph.D statisticians
- 2 *Ex officio members* – IRB Chair, Director of Research Integrity (official institutional liaison)
- Expert reviewers on an as per needed basis

Process

- Institutional officials in consultation w/chair identify potential members—strong methodological skills key
- Members are compensated
- Members terms – initial one year appointment;
- Members serve at the pleasure of the institutional officials

Introduction

- What is the SRC?
- Which Protocols are Reviewed?
- What is the SRC Process?
- Tips on getting through the SRC

Overview

- Federal regulations require the institution to be certain that all human studies research has scientific merit
- IRB focuses on ethical issues

What is the SRC?

- The scientific Review Committee (SRC) established to reinforce institutional mission to promote research excellence.
- The SRC reviews selected clinical research proposals to ensure they meet acceptable standard of scientific rigor and merit prior to IRB review.

SRC Procedures: Protocol Selection

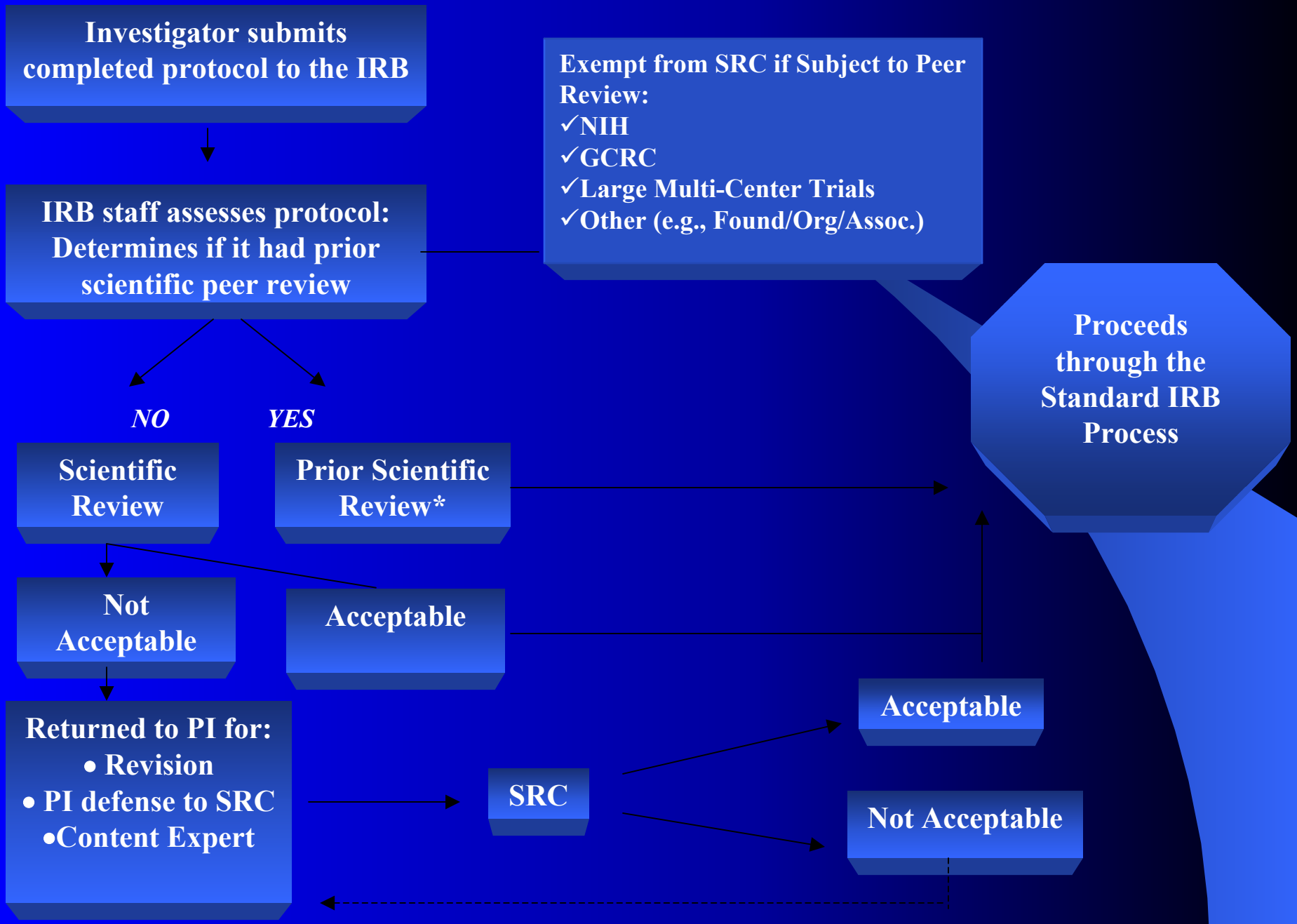
- IRB staff and SRC select protocols for review.
- Goal: assure all research has had independent scientific review prior to going to the IRB.

Examples of protocols NOT reviewed

- Federally funded Research e.g.,DoD; DoE; EPA; DHHS, AHRQ, CDC, FDA, NIH; DoJ,etc..
- General Clinical Research Center protocols (GCRC) - approved by its Scientific Advisory Committee.
- Minimal Risk – Research that qualifies for expedited or exempt IRB review

Other Exceptions

- Research funded by corporate, foundation/organization/association using an adequate peer review mechanism.
- The IRB and/or Institutional Officials may, at their discretion, forward any protocol to SRC at any point during review process.


Investigator submits completed protocol to the IRB
IRB staff assesses protocol: Determines if it had prior scientific peer review
Exempt from SRC if Subject to Peer Review:
✓NIH
✓GCRC
✓Large Multi-Center Trials
✓Other (e.g., Found/Org/Assoc.)
Proceeds through the Standard IRB Process
NO
YES
Scientific Review
Prior Scientific Review*
Not Acceptable
Acceptable
Returned to PI for:
• Revision
• PI defense to SRC
•Content Expert
SRC
Acceptable
Not Acceptable

SRC Procedures: Protocol Review

- Meets weekly
- 2 Primary reviewers: MD and statistician
- Expert invited if necessary
- Review criteria on Tufts/Tufts-NEMC website

SCIENTIFIC REVIEW COMMITTEE
PROTOCOL REVIEW AND MONITORING SYSTEM

Protocol Review Form

Scientific Reviewer Comments – (page 1 of 2)

Title:

PRINCIPAL INVESTIGATOR: Reviewer:

Objectives: Clearly stated purpose of study

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Background and Rationale: Justification for conducting the study; results of similar or pilot data; current literature cited

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Design: Adequate to determine stated objectives

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Eligibility Criteria: Specific inclusion/exclusion requirements

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Outcome Characteristics and Endpoint Definitions:

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Statistical Analysis and Sample Size:

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Data Management:

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Data and Safety Management Plan:

Present/Acceptable Present/ Not Acceptable Absent

Comment:

Overall Assessment:

Forward to IRB for consideration Forward to IRB with comments Return to PI with comments

Comment:

Please summarize below at end of committee discussion what changes you request or questions you want conveyed to the PI:

Content Experts

- Called for if specific question arises
- SRC chair notifies Division Chief
- Reviewers must
  - Not be involved in protocol
  - Be willing
  - Be available to attend SRC meeting

Content Experts (cont'd)

- Experts are requested to:
  - Assess relevance of proposed study to the field; or
  - Assess technical issues beyond expertise of committee members.
- Expert reviewer addresses specific questions posed by SRC members.
- Reviewer does not provide written comments.
- Reviewer excused prior to members discussion.

SRC Procedures: Decisions

- Approved - sent to IRB for consideration
- Approved with stipulations – sent to IRB with comments
- Not yet approvable - return to PI

SRC Experience to Date:

- Problem protocols:
  - Often submitted by trainees
  - Do not contain all relevant sections of a research protocol
  - Measures do not match objectives
  - Analytic plan missing or vague
  - Concern about the validity of the scientific question

Protocol Reviews

- 25 proposed studies reviewed by the SRC prior to the "go live" date (May 2003 thru January 2004)
- Since go live (2/1/04), five studies for SRC review
- Two studies awaiting review – 4/23/04
- 5 protocols reviewed since 2/1/04, 3 returned to PI; 2 forwarded to the IRB with comments

Summary – SRC Process

- SRC provides independent scientific review of clinical protocols not previously reviewed
- SRC decisions are binding
- Procedures designed to minimize delay for acceptable protocols

Expected Outcomes

- Enhance quality of research at Tufts & Tufts-NEMC
  -increase IRB protocols that result in published papers
- Referral to institutional clinical research resources for assistance
  -count the referrals from the SRC

Expected Outcomes (cont'd)

- Eliminate initial IRB review of inadequate protocols: incomplete, poorly designed, improperly powered, etc.
  -eliminate deferrals for these reasons
- Enable the IRB to focus on ethical concerns
  -eliminate deferrals for scientific concerns

No Pain, No Gain

- Data collection completed
- Working on the analysis
- Discover design flaw – after the fact
- UGH!
- Better to be Proactive v. Reactive:
  Input effort upfront