Scientific & Scholarly Validity Review

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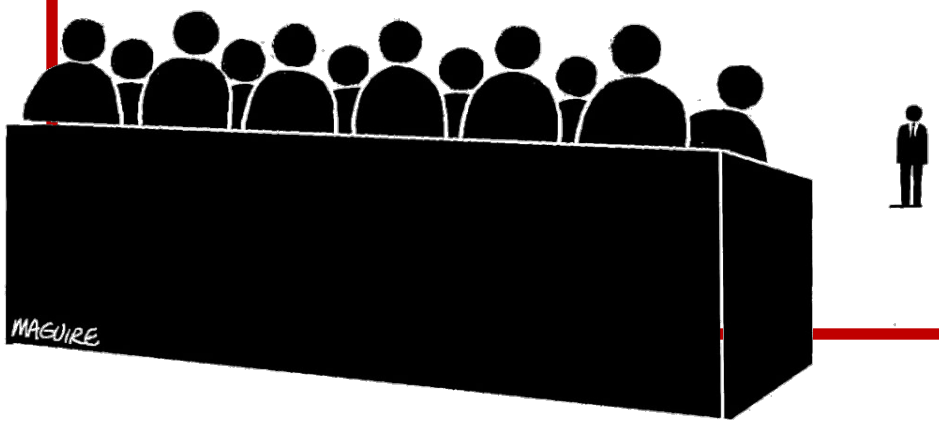
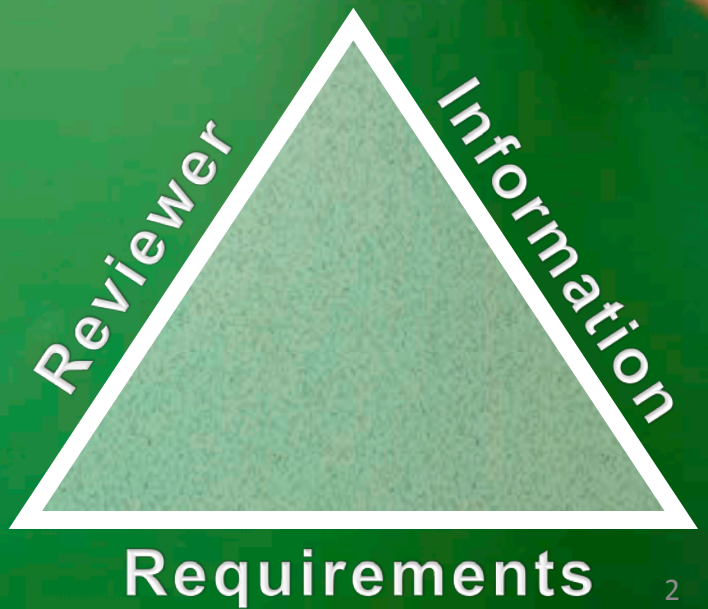


Today's Topics

- Where do we get our requirements?
- Who do we rely on for the review?
- Scientific and scholarly review questions
- Final Determination



Requirements for Scientific/Scholarly Review

- Code of Federal Regulations
- AAHRPP Element I.1.F

Code of Federal Regulations

45 CFR 46.111(a)(1,2) & 21 CFR 56.111(a)

Risks to subjects are minimized:

(i) By using **procedures which are**

a. consistent with **sound research design**, and

b. which **do not unnecessarily expose subjects to risk**,

(ii) And, whenever appropriate, by using procedures **already being performed** on the subjects for diagnostic or treatment purposes

Code of Federal Regulations

- **Risks to subjects are reasonable**
  - in relation to **anticipated benefits**, if any, to subjects,
  - and the **importance of the knowledge** that may reasonably be expected to result."

AAHRPP

Element I.1.F

The Organization has and follows **written policies and procedures** for reviewing the scientific or scholarly validity of a proposed research study.

Such procedures are **coordinated** with the ethics review process.

Who Provides the Review?
The IRB relies on…

Federally sponsored research	Competitive peer review process
FDA research (most industry - sponsored)	FDA (during IND or IDE evaluation)
VA Research	VA R & D Committee
CTRU (Clinical Translational Research Unit)	CTRU Advisory Committee
Cancer Center	SRC (Scientific Review Committee)
Other research (non-funded or student research)	Department Chair, Division Chief, Faculty Sponsor, School Dean (or designee)

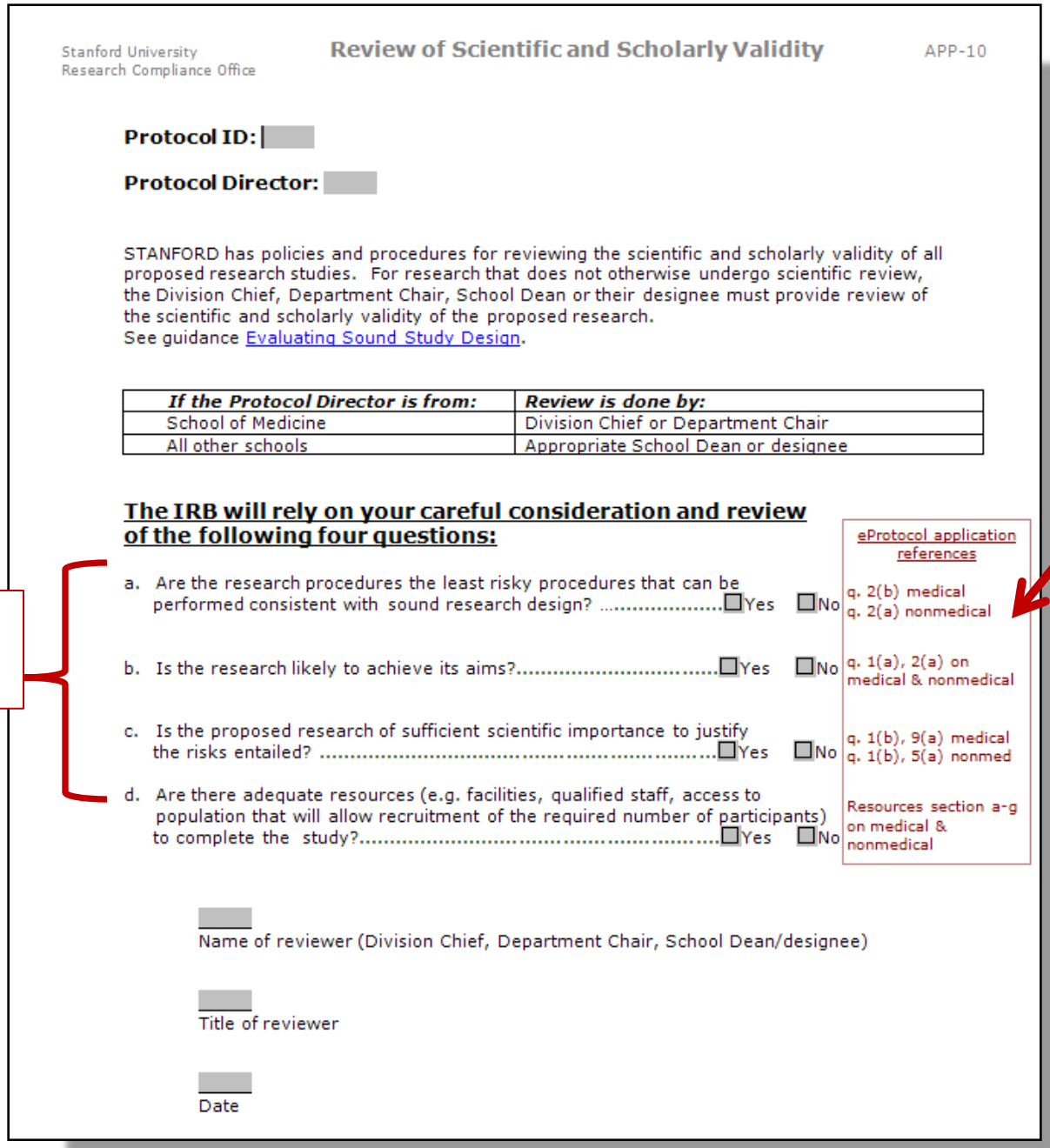
Scientific and Scholarly Review Questions

"We rely on the reviewers' responses to these questions:"

"REVIEW OF SCIENTIFIC AND SCHOLARLY VALIDITY*"

**APP-9, APP-10*

a. Does the study use **least risky procedures** consistent with **sound research design**?
b. Will it likely achieve its **aims**?
c. Is it of enough **scientific importance** to justify the risks?
d. Are there **adequate resources** to complete the study?



Stanford University
Research Compliance Office

Review of Scientific and Scholarly Validity

APP-10

Protocol ID:

Protocol Director:

STANFORD has policies and procedures for reviewing the scientific and scholarly validity of all proposed research studies. For research that does not otherwise undergo scientific review, the Division Chief, Department Chair, School Dean or their designee must provide review of the scientific and scholarly validity of the proposed research.
See guidance Evaluating Sound Study Design.

If the Protocol Director is from:	*Review is done by:*
School of Medicine	Division Chief or Department Chair
All other schools	Appropriate School Dean or designee

The IRB will rely on your careful consideration and review of the following four questions:

		eProtocol application references
a.	Are the research procedures the least risky procedures that can be performed consistent with sound research design? ☐Yes ☐No	q. 2(b) medical q. 2(a) nonmedical
b.	Is the research likely to achieve its aims? ☐Yes ☐No	q. 1(a), 2(a) on medical & nonmedical
c.	Is the proposed research of sufficient scientific importance to justify the risks entailed? ☐Yes ☐No	q. 1(b), 9(a) medical q. 1(b), 5(a) nonmed
d.	Are there adequate resources (e.g. facilities, qualified staff, access to population that will allow recruitment of the required number of participants) to complete the study? ☐Yes ☐No	Resources section a-g on medical & nonmedical

Name of reviewer (Division Chief, Department Chair, School Dean/designee)

Title of reviewer

Date

4 questions

eProtocol references

Documentation of Scientific and Scholarly Validity

"Scientific Review Protocol Form*

PD answers the following questions:

1) Study Name
2) PI/personnel
3) Funding
4) Sources where PD is seeking funding
5) Specific Aims/hypothesis
6) General background
7) Preliminary data
8) Experimental design
9) Significance
10) Key References

Information is also found in the eProtocol application – any member can ask for this form

* NOT-13

Is PD a student?

NO

Is PD a faculty member/staff?

Manager must get documentation that review was done prior to approval

YES

Faculty Sponsor -answers 4 questions

YES

Does scientific review take place via SRC, VA, etc.?

YES

IRB relies on the entity's scientific and scholarly review

NO

Does the study involve med/high risk?

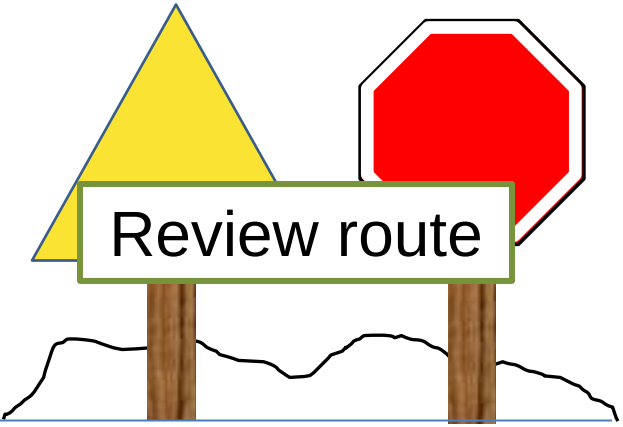
NO

No *"Scientific Review Protocol"* form required

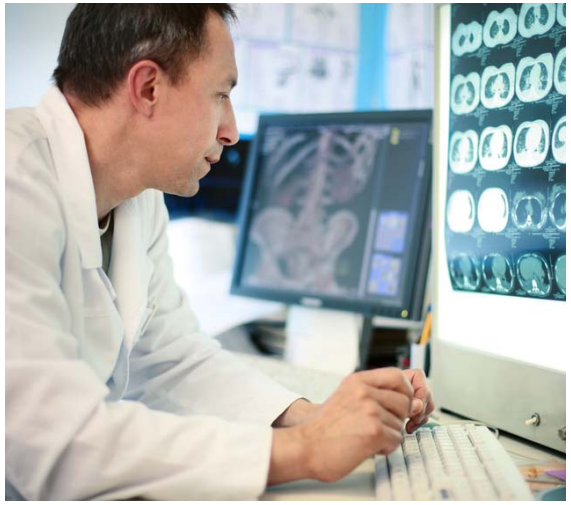
YES

A *"Scientific Review Protocol"* form is submitted

Chair/Div. Chief does review (or Dean) answers 4 questions



IRB Expertise



"An IRB may, (at) its discretion, **invite individuals with competence in special areas** to assist in the review of issues which require expertise beyond or in addition to that available on the IRB…"

**45 CFR 46.107*

HRPP 6.5 Obtaining Additional Expertise

- IRB Chair (or the…reviewer) can ask experts in specific areas to assist in evaluating issues that require expertise beyond or in addition to that available on the IRB.

- Reasons for seeking…outside experts may include the need for:

  - ❖ **additional** scientific, clinical, or scholarly **expertise**;
  - ❖ knowledge and understanding about potentially **vulnerable** populations of **subjects**;
  - ❖ **desire** to ensure **appropriate consideration** of race, gender, language, cultural background, and sensitivity to such issues as community attitudes

Who else can determine the scientific/scholarly validity?

What if Scientific and Scholarly Validity can't be established?

- Re-consider after modifications
- Disapprove

The IRB **should not approve** a research protocol that **involves risks** if:

- objectives can be achieved through procedures that **pose less risks** to participants
- it is **not designed** to **ask a question** that is **important**
- asks a question that has **already been answered** by prior research, or
- will likely yield **results of no** discernible **value**

- There are considerations for low/no risk studies

GUI-17, “Evaluating Sound Study Design”

Resources

- HRPP Chapter 1.7 and 6.5
- NOT-13: “Scientific Review Protocol for HSR “(for projects not otherwise undergoing Scientific Review)
- APP-10 “Review of Scientific and Scholarly Validity”
- APP-9 “Review of Scientific and Scholarly Validity and Oversight”
- GUI-17 “Evaluating Sound Study Design”
- VAPAHCS Memorandum No. 151-05-08, “R & D Committee and Associated Subcommittees”