

IRB Actions

- The committee discusses the study following the presentation of the Primary and secondary reviewers' evaluation and comments.
- The Primary Reviewer includes a recommendation for a motion in their Review.
- Following the committee discussion, a final motion is made...





Committee Actions

Approve

Approve with Contingencies, Designated Reviewer

Approve with Contingencies, Staff Verifiable

Defer

Disapprove

Committee Actions

Approve

The study as written **meets all criteria for approval** with no further changes



Committee Actions

Approve with Contingencies, Designated Reviewer

The board finds that the application is “approvable” with modifications, clarifications, and/or verifications, examples:

- 1) confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted;
- 2) submission of additional documentation;
- 3) precise language changes to protocol or informed consent documents; or
- 4) substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

This may be a chair, committee member, or IRB analyst with appropriate experience or expertise

Committee Actions

Approve with Contingencies, Staff Verifiable

If changes proposed are **administrative/editorial** in nature, **NOT** part of the approval criteria then no additional IRB review is needed, and the changes can be reviewed as part of the verification process.

The contingency cannot be tied to a judgement or justification.

Examples: confirmation of ancillary approvals, site permission, HRPO approval, check a box, very precise changes to a document, CTO.

This is less about “who” reviews as it is about the nature of the contingency

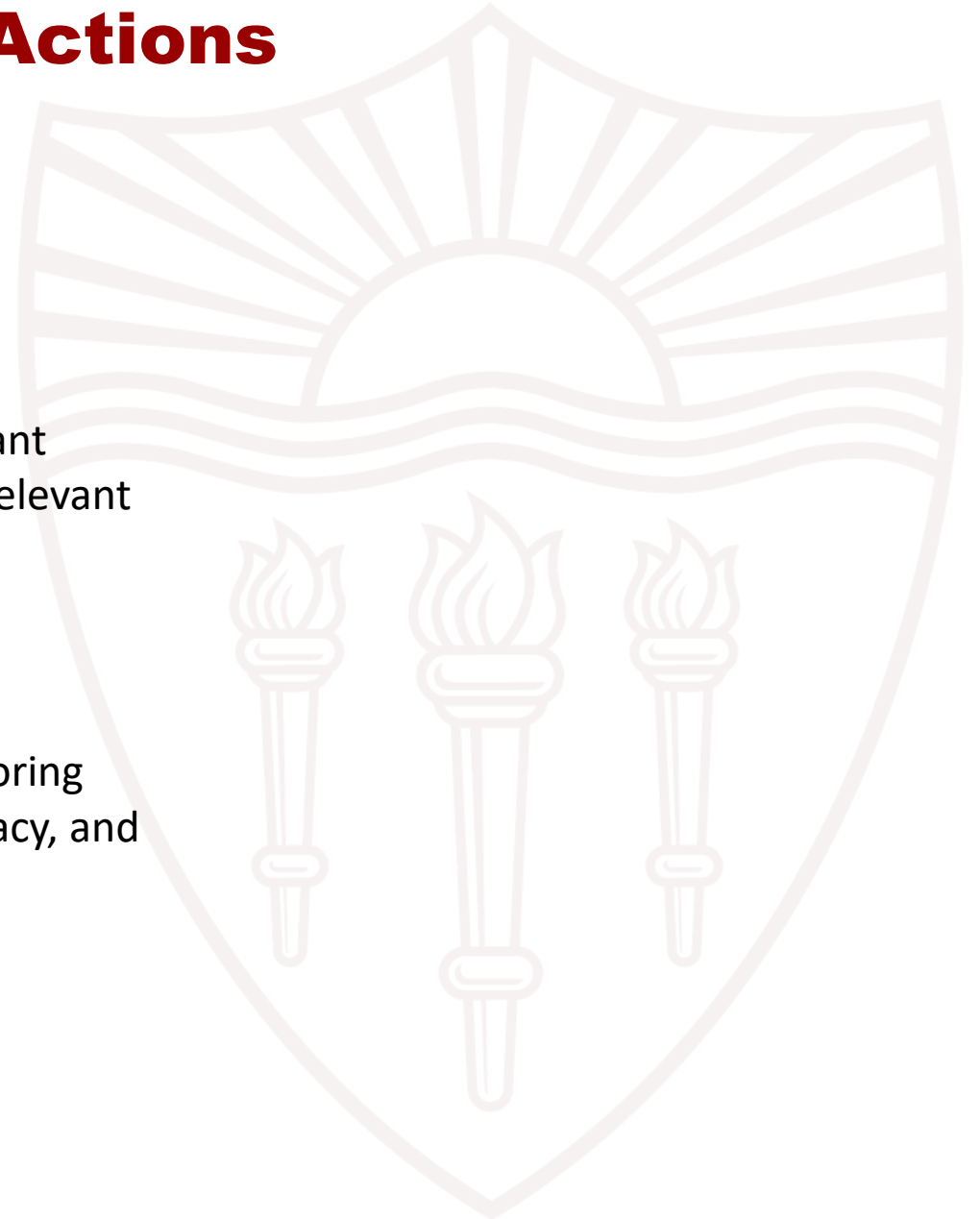
Committee Actions

Defer

The board has serious concerns about the study or significant information or modifications are needed that are directly relevant to the criteria for approval.

Examples:

More than minor questions about the risks, research design/methodology, statistical analysis, data safety monitoring plan, provisions for protecting participant's safety and privacy, and informed consent documents.



Committee Actions

Disapprove

The protocol describes research activities that may pose significant concerns for human participant safety with minimal prospect of benefit

The risk to benefit ratio is deemed unfavorable



Is it a designated reviewer contingency or staff verifiable contingency?

- 1) *Confirm that the IP address will not be recorded.*
- 2) *Clarify who will be performing the arterial blood gas draw.*
- 3) *Please upload the HRPO review document once obtained.*
- 4) *Please revise the risk section of the consent to include lay terms for neutropenia and thrombocytopenia.*

[Approve](#)

Approve w/ contingencies, [designated reviewer](#)

Approve w/contingencies, [staff verifiable](#)

[Defer](#)

[Disapprove](#)

Where Can I Find More Information?

- USC HRPP Website
 - [Policies](#)
 - [IRB Member Toolbox](#)

- IRB Member Regulatory Reference Guide (attached with meeting agenda)

- Code of Federal Regulations
 - [45 CFR 46.111](#)
 - [21 CFR 56.111](#)

- IRB Member Handbook (Amdur/Bankert)

IRB Member Toolbox
Password protected page for IRB Members only.

Office of Research
Office for the Protection of Research Subjects
Institutional Review Board

IRB Member Regulatory Reference Guide
Criteria for Approval and Board Determinations

Criteria for IRB Approval of Research
45 CFR 46.111 and 21 CFR 56.111

1) Risks to subjects are minimized

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) 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.

3) Selection of subjects is equitable

4) Informed consent will be sought from each subject or the subject's legally authorized representative (if allowable)

5) Informed consent will be documented

6) Research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects

7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

8) Additional safeguards have been included in the study to protect the rights and welfare of vulnerable subjects

Board Determinations

- **Approved:** Meets criteria for approval, no changes required.
- **Approved with Contingencies (Designated Review):** The application is approvable with modifications, clarifications or verifications requiring medical, scientific, or technical expertise. Examples include:
 - (i) Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted
 - (ii) Submission of additional documentation
 - (iii) Precise language changes to protocol or informed consent documents; or
 - (iv) Substantive changes to protocol or informed consent documents along with clearly stated parameters that the change meet safety
- **Approved with Contingencies (Staff Verifiable):** Review of the contingencies does not require special expertise and an administrative official can be done in situ.
- **Deferred:** The board has serious concerns about the study, and/or requires significant modifications before the study meets the criteria for approval under 45 CFR 46.111/21CFR 56.111. The principal investigator must submit the requested additional information for IRB Board review. Examples of significant modifications include more than minor changes to the risks, research design and methodology, statistical analysis, data safety monitoring plan, provisions for protecting human subjects' safety and privacy, and informed consent document(s).
- **Tabled:** The board is unable to discuss the study due to lack of time or loss of quorum. The application is placed on the agenda for the next convened meeting.
- **Disapproved:** The protocol does not provide adequate protection to human participants, and it is unlikely that it can be modified to provide such protection. The IRB notifies the principal investigator of the disapproval in writing, including a statement of the reasons for its decision.

Chapter 7: Process of IRB Submissions

Revised on 3/28/2024

This chapter focuses on the IRB submission and review processes. It includes an overview of iStar, the electronic application system used to submit all human subjects proposals to the IRB, the criteria for IRB approval, the review process for the different submission types, and IRB determinations and correspondence details.

- ▼ **7.1 IRB Online Applications (iStar)**
- ▼ **7.2 ClinicalTrials.Gov**
- ▼ **7.3 Criteria for IRB Approval of Research**

 **Code of Federal Regulations**
A point in time eCFR system 

FOURTH EDITION

Institutional Review Board
MEMBER HANDBOOK

Robert Amdur
Elizabeth A. Bankert

IRB Review Actions

Thank You!