USC University of Southern California

# IRB Actions

USC Research and Innovation
*Human Research Protection Program*

May 2024

- 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…



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45 CFR 46. 111 Criteria for IRB approval of research (DHHS)
21 CFR 56.111 Criteria for IRB approval of research (FDA)

# 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

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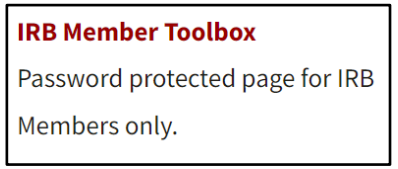
# Where Can I Find More Information?

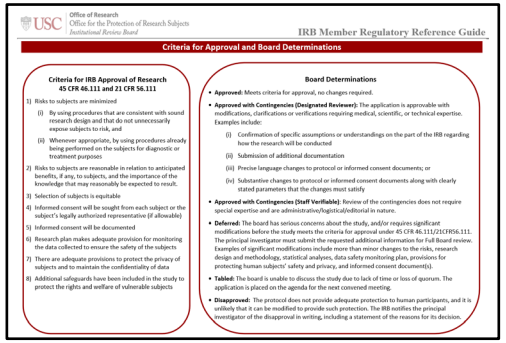
- USC HRPP Website
  - Policies
  - IRB Member Toolbox

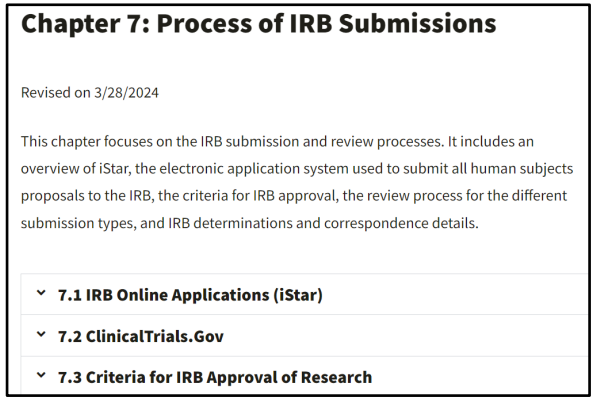
- IRB Member Regulatory Reference Guide (attached with meeting agenda)

- Code of Federal Regulations
  - 45 CFR 46.111
  - 21 CFR 56.111

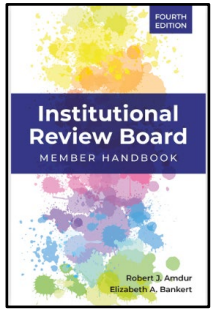
- IRB Member Handbook (Amdur/Bankert)







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# IRB Review Actions

Thank You!

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