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...

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.
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.
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 Review Actions

Thank You!