HUA HUMAN RESEARCH PROTECTION PROGRAM

IRB MEETINGS

BEFORE

HRP-040 MEETING PREPARATION



HRP-040 MEETING PREPARATION



IRB Coordinator must:



PREPARE pre-review materials



COMPOSE private comment



ATTACH associated documents

HRP-040 MEETING PREPARATION

CONFIRMATION

- Attendance
- Experience, expertise
- Quorum
 - Scientist
 - Non-Scientist
 - Non-Harvard
 - Community perspective

PREPARATION

- Assign reviewers
 - Scientific/scholarly review
- Continuing education
- Expedited actions
- Tinkering
- And send!

DURING

HRP-041 MEETING CONDUCT



HRP-041 MEETING CONDUCT

HRP-340 WORKSHEET: IRB

Meeting Documentation Aid:

- Recusals for COIs
- Consultant presentation
- Consideration of Criteria for Approval

	Meeting Date
1	MEETING INFORMATION
	Verification of Voting Members' Attendance
	Verification Quorum is Reached (including Non-Scientist Voting Member)
	Conflict of Interest Reminder
	Review of Meeting Minutes from
	Revisions needed:
	□ No Revisions needed; Minutes Accepted
	Notation of the Expedited Actions completed within the past 45 days
	Review of Other Business Items
	Continuing Education Topic:
2	AGENDA ITEM #1:
	Presentation by Primary Reviewer ()_
	Presentation by Secondary Reviewer () – Leave unchecked if no Secondary Review
	Additional Comments from IRB Administrator (
	Open Discussion by all Board Members
	Motion by Primary Reviewer
	☐ Approve with no Conditions – See additional items to be noted
	☐ Modifications Required to Secure Approval (Conditional Approval) – See additional ite
	□ Deferral
	☐ Disapprove – If <u>Disapprove</u> , identify concerns according to the Belmont Principle
	Seconding of Primary Reviewer's Motion
	Determination of additional items, as applicable, for an Approval or Conditional Approval

FULL BOARD REVIEW ACTIONS







Modifications Required to

Secure Approval

Meets Criteria for Approval

(HRP-314 WORKSHEET)

Deferral

May meet Criteria for Approval

(HRP-314 WORKSHEET)

Disapproval

Does not meet Criteria for Approval

(HRP-314 WORKSHEET)

Violation of Belmont Report

...STILL DURING

HRP-042 MEETING ATTENDANCE MONITORING



BEGINS ENDS MEETING ADJOURNED



AFTER

HRP-043 MEETING MINUTES



BEGINS ENDS MINUTES APPROVED @ NEXT MEETING

Risk level

Approval period

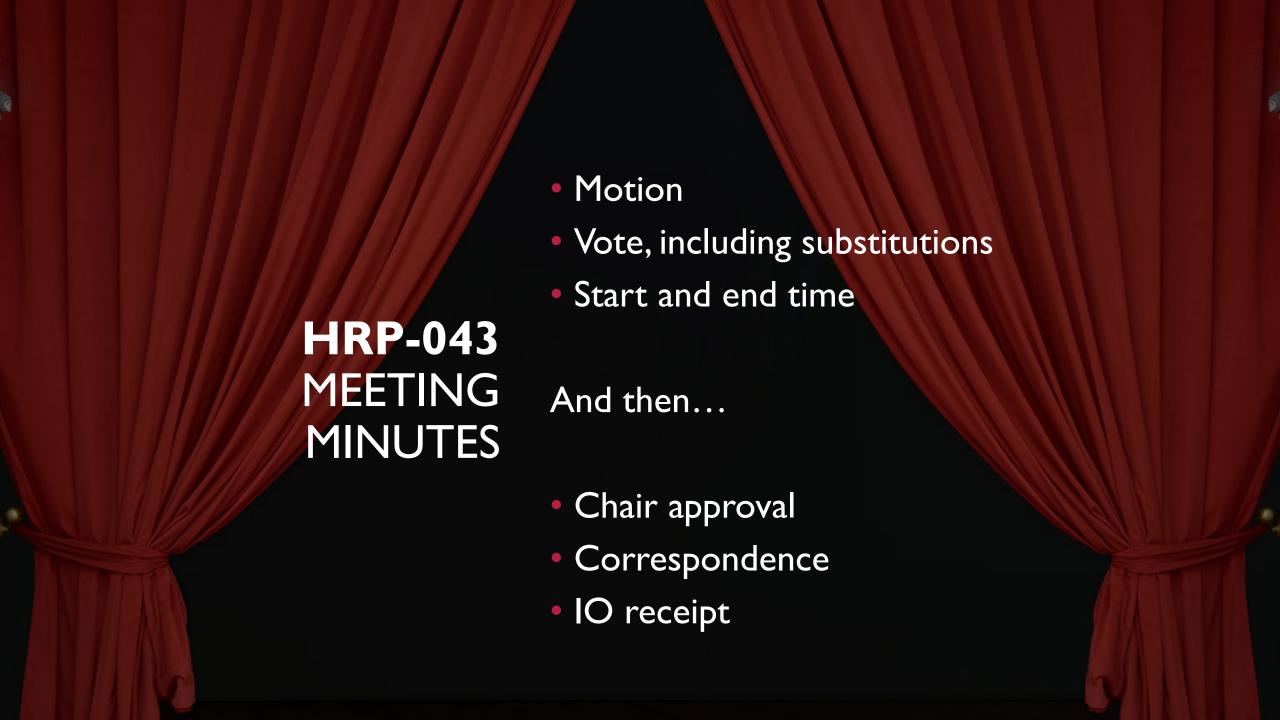
Recommended changes and reasons

Controverted issues

Regulatory determinations, including RNI

Supporting documents like checklists

HRP-043MEETING MINUTES



IRB MEETINGS BY THE NUMBERS

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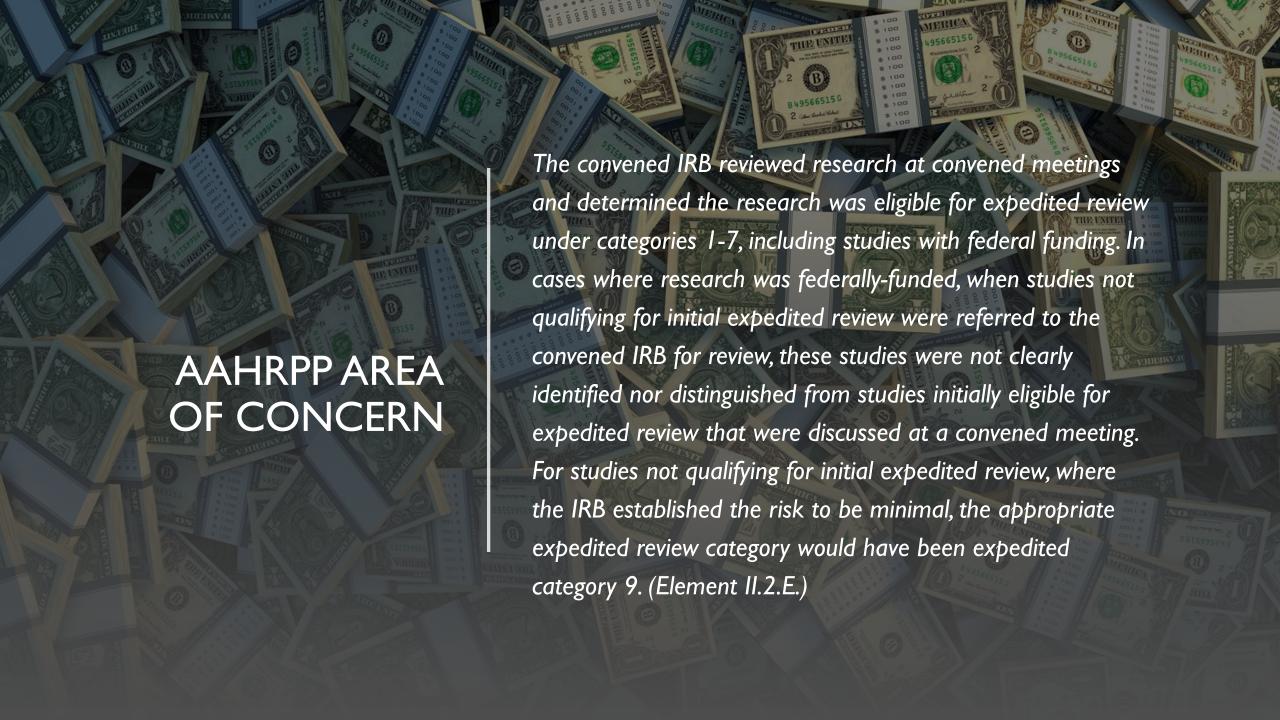
Votes made by non-Member consultant

01

Number of votes allowed for a Member and their Alternate 04

Quorum for 6 Voting Members 07

Days between agenda and meeting/meeting and minutes



HUA IRB RESPONSE

- Actions:
 - IRB meeting agenda and minutes to state if federally funded and/or subject to FDA oversight
 - If not federally funded and/or subject to FDA oversight—no impact on process
 - Employ all Expedited categories
 - No additional categorization required
 - If federally funded and/or subject to FDA oversight:
 - Employ Expedited category 9 only for minimal risk research
 - IRB meeting agenda and minutes will clearly distinguish which studies do not qualify for initial expedited review from those studies initially eligible for expedited review still discussed at a convened meeting

AAHRPP AREA OF CONCERN

When the convened IRB reviewed research that planned to enroll prisoners or children, neither the minutes nor the IRB checklist documented that the Board made protocol-specific determinations of additional protections for vulnerable populations. In two studies involving children and one study involving prisoners, the IRB staff prepared the checklist by copying relevant justification from the protocol. No documentation existed in the checklist or meeting minutes that provided protocol-specific determinations by the convened IRB providing the rationale why the convened IRB concurred with the rationale provided by the investigator. (Element II.5.B.)

HUA IRB RESPONSE

Actions:

- "To ensure there is documentation that the Convened IRB discussed and assessed these checklists in studies where Children and/or Prisoners will be enrolled, HRP-43—SOP— HUA—IRB Meeting Minutes has been revised.
- The minutes will be used to state whether the IRB concurred with the information in the prepared checklist, which may include justifications provided by the investigator, and the protocol-specific rationale for why.
- Any requests for revision to the prepared checklists will be documented in the minutes as well."