

HUA HUMAN RESEARCH PROTECTION PROGRAM

IRB MEETINGS



BEFORE

HRP-040

MEETING PREPARATION



BEGINS

AGENDA IS CLOSED

ENDS

AGENDA MATERIALS SENT

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



BEGINS
MEETING CONVENED

ENDS
MEETING ADJOURNED

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 | |
| <input type="checkbox"/> | Verification of Voting Members' Attendance |
| <input type="checkbox"/> | Verification Quorum is Reached (including Non-Scientist Voting Member) |
| <input type="checkbox"/> | Conflict of Interest Reminder |
| <input type="checkbox"/> | Review of Meeting Minutes from [REDACTED] |
| <input type="checkbox"/> | Revisions needed: [REDACTED] |
| <input type="checkbox"/> | No Revisions needed; Minutes Accepted |
| <input type="checkbox"/> | Notation of the Expedited Actions completed within the past 45 days |
| <input type="checkbox"/> | Review of Other Business Items |
| <input type="checkbox"/> | Continuing Education Topic: [REDACTED] |
| 2 AGENDA ITEM #1: | [REDACTED] |
| <input type="checkbox"/> | Presentation by Primary Reviewer ([REDACTED]) |
| <input type="checkbox"/> | Presentation by Secondary Reviewer ([REDACTED]) – Leave unchecked if no Secondary Review |
| <input type="checkbox"/> | Additional Comments from IRB Administrator ([REDACTED]) |
| <input type="checkbox"/> | Open Discussion by all Board Members |
| <input type="checkbox"/> | Motion by Primary Reviewer |
| <input type="checkbox"/> | Approve with no Conditions – <i>See additional items to be noted</i> |
| <input type="checkbox"/> | Modifications Required to Secure Approval (Conditional Approval) – <i>See additional it</i> |
| <input type="checkbox"/> | Deferral |
| <input type="checkbox"/> | Disapprove – <i>If Disapprove, identify concerns according to the Belmont Principle</i> |
| <input type="checkbox"/> | Seconding of Primary Reviewer's Motion |
| <input type="checkbox"/> | 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

For more information see **HRP-103** HUA Investigator Manual and “Before You Begin to Prepare Your IRB Application” in the **IRB Lifecycle** at cuhs.harvard.edu

...STILL DURING

HRP-042

MEETING ATTENDANCE MONITORING



| | |
|-----------------|-------------------|
| <u>BEGINS</u> | <u>ENDS</u> |
| QUORUM OBTAINED | MEETING ADJOURNED |



QUORUM AND EXPERTISE

AFTER

HRP-043

MEETING MINUTES



BEGINS ENDS
MEETING CONVENED MINUTES APPROVED @ NEXT MEETING

Risk level

Approval
period

Recommended
changes and
reasons

Controverted
issues

Regulatory
determinations,
including RNI

Supporting
documents like
checklists

HRP-043
MEETING MINUTES



HRP-043 MEETING MINUTES

- Motion
- Vote, including substitutions
- Start and end time

And then...

- Chair approval
- Correspondence
- IO receipt

IRB MEETINGS BY THE NUMBERS

00

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

The background of the slide is a dense, overlapping field of US dollar bills, including one-dollar and two-dollar bills, scattered across the entire surface. The bills are slightly blurred and have a dark, semi-transparent overlay applied to them, making the text legible.

AAHRPP AREA OF CONCERN

The convened IRB reviewed research at convened meetings and determined the research was eligible for expedited review under categories 1-7, including studies with federal funding. In cases where research was federally-funded, when studies not qualifying for initial expedited review were referred to the convened IRB for review, these studies were not clearly identified nor distinguished from studies initially eligible for expedited review that were discussed at a convened meeting. For studies not qualifying for initial expedited review, where the IRB established the risk to be minimal, the appropriate expedited review category would have been expedited category 9. (Element II.2.E.)

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.”