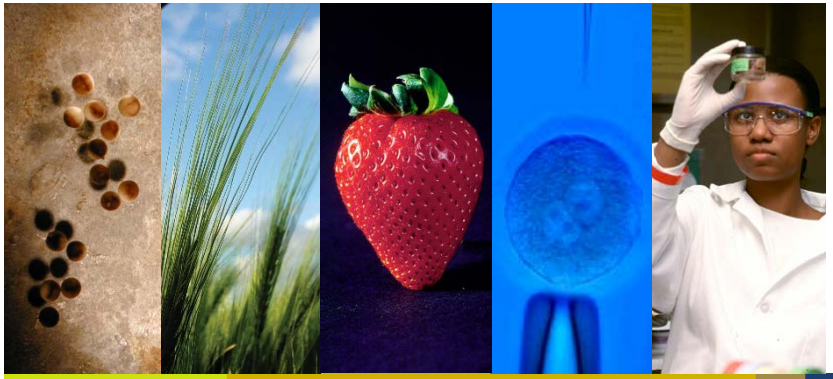


UC DAVIS OFFICE OF RESEARCH

Choosing Determinations for New Studies, Modifications, and Renewals

UCDAVIS
OFFICE OF RESEARCH

Objectives

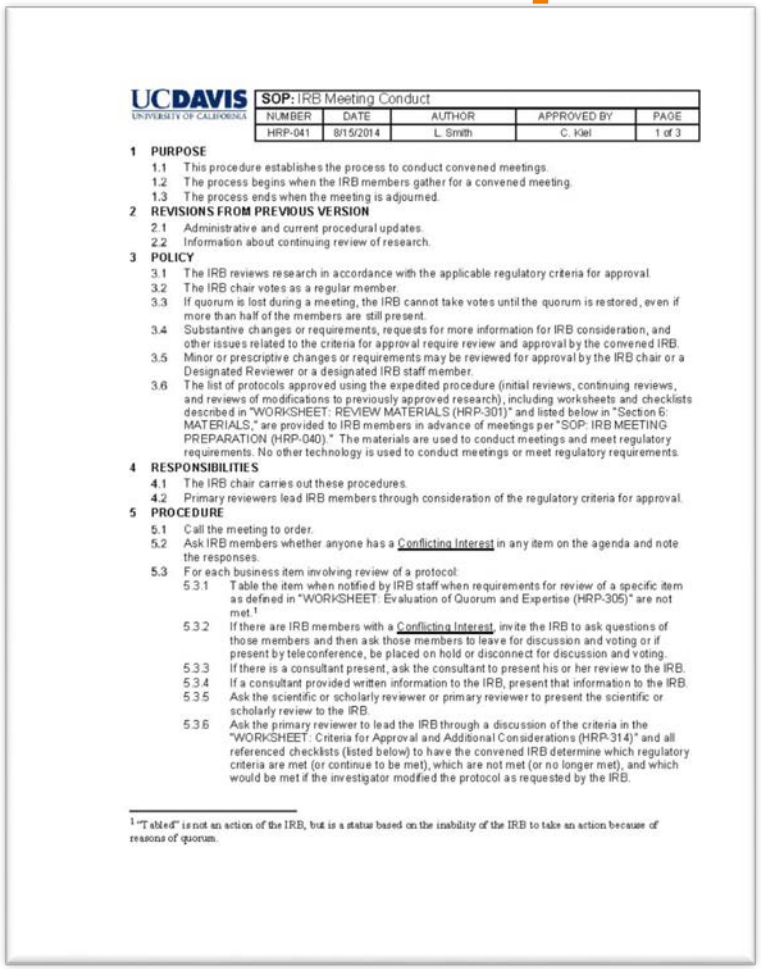
- Review the IRB Standard Operating Procedure for Meeting Deliberations and Determinations
- Describe Determination Options and the Applicability of Each
- Relate Determinations to Criteria of Approval

Determinations Matter:

- Determinations are the embodiment of actions to protect human subjects in research and basis of correspondence with Researchers
- Determinations form the content of IRB minutes
- Determinations are subject to audit by the FDA, OHRP, and UC Davis
- Determinations form a public record subject to inspection

UCDAVIS
OFFICE OF RESEARCH

Standard Operating Procedure for



UCDAVIS UNIVERSITY OF CALIFORNIA

SOP: IRB Meeting Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	8/15/2014	L. Smith	C. Kiel	1 of 3

1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.
1.2 The process begins when the IRB members gather for a convened meeting.
1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Administrative and current procedural updates.
2.2 Information about continuing review of research.

3 POLICY

3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
3.2 The IRB chair votes as a regular member.
3.3 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
3.4 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
3.5 Minor or prescriptive changes or requirements may be reviewed for approval by the IRB chair or a Designated Reviewer or a designated IRB staff member.
3.6 The list of protocols approved using the expedited procedure (initial reviews, continuing reviews, and reviews of modifications to previously approved research), including worksheets and checklists described in "WORKSHEET: REVIEW MATERIALS (HRP-301)" and listed below in "Section 6: MATERIALS," are provided to IRB members in advance of meetings per "SOP: IRB MEETING PREPARATION (HRP-040)." The materials are used to conduct meetings and meet regulatory requirements. No other technology is used to conduct meetings or meet regulatory requirements.

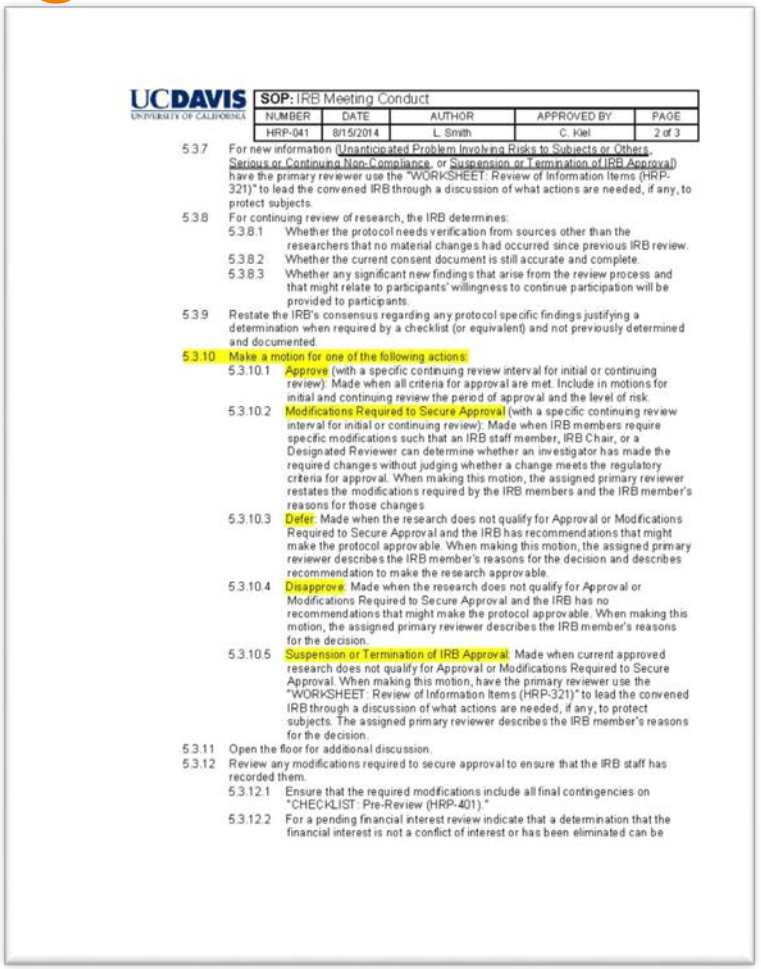
4 RESPONSIBILITIES

4.1 The IRB chair carries out these procedures.
4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE

5.1 Call the meeting to order.
5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
5.3 For each business item involving review of a protocol:
5.3.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in "WORKSHEET: Evaluation of Quorum and Expertise (HRP-305)" are not met.[1]
5.3.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.
5.3.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.
5.3.4 If a consultant provided written information to the IRB, present that information to the IRB.
5.3.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
5.3.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the "WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)" and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

[1] "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.



UCDAVIS UNIVERSITY OF CALIFORNIA

SOP: IRB Meeting Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	8/15/2014	L. Smith	C. Kiel	2 of 3

5.3.7 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or Suspension or Termination of IRB Approval) have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.
5.3.8 For continuing review of research, the IRB determines:
5.3.8.1 Whether the protocol needs verification from sources other than the researchers that no material changes had occurred since previous IRB review.
5.3.8.2 Whether the current consent document is still accurate and complete.
5.3.8.3 Whether any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.
5.3.9 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist (or equivalent) and not previously determined and documented.
5.3.10 Make a motion for one of the following actions:
5.3.10.1 Approve (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.
5.3.10.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): Made when IRB members require specific modifications such that an IRB staff member, IRB Chair, or a Designated Reviewer can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes.
5.3.10.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.
5.3.10.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.
5.3.10.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.
5.3.11 Open the floor for additional discussion.
5.3.12 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
5.3.12.1 Ensure that the required modifications include all final contingencies on "CHECKLIST: Pre-Review (HRP-401)."
5.3.12.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be

UCDAVIS OFFICE OF RESEARCH

Main IRB Determinations

Determination	Meaning
Approval 	Ethical criteria are satisfied for the conduct of research. Research can begin when all other institutional approvals have been obtained.
Approval with Administrative Comm 	Ethical criteria are satisfied for the conduct of research. Research can begin when all other institutional approvals have been obtained. The IRB provides an administrative comment about some aspect of the project or its conduct outside of criteria for approval.
Approval with Modifications Required 	The IRB requires modifications in order to approve the research. Research cannot commence until a final approval is received.
Deferral 	The IRB cannot approve the research as submitted and describes reasons or modifications that might make the research approvable; the IRB requests additional information from the researcher.
Disapproval 	The IRB cannot approve the research as submitted and cannot describe modifications that might make the research approvable.
Exempt 	Certain categories of Human Research may be exempt from regulation but require IRB review; the institution, not the researcher, determines exemption.
UC Davis is Not Engaged 	UC Davis is not engaged such that a particular non-exempt human subjects research project or activity is not subject to IRB oversight.
Not Human Subjects Research 	Activities that do not meet the Institutional definition of "Human Research" are not subject to IRB oversight.

Hold On.

Some studies are not ready for review in Full Committee...

Committee Analysts can move a study to a future committee meeting agenda if it is not ripe for review or if it "misses" the boat.

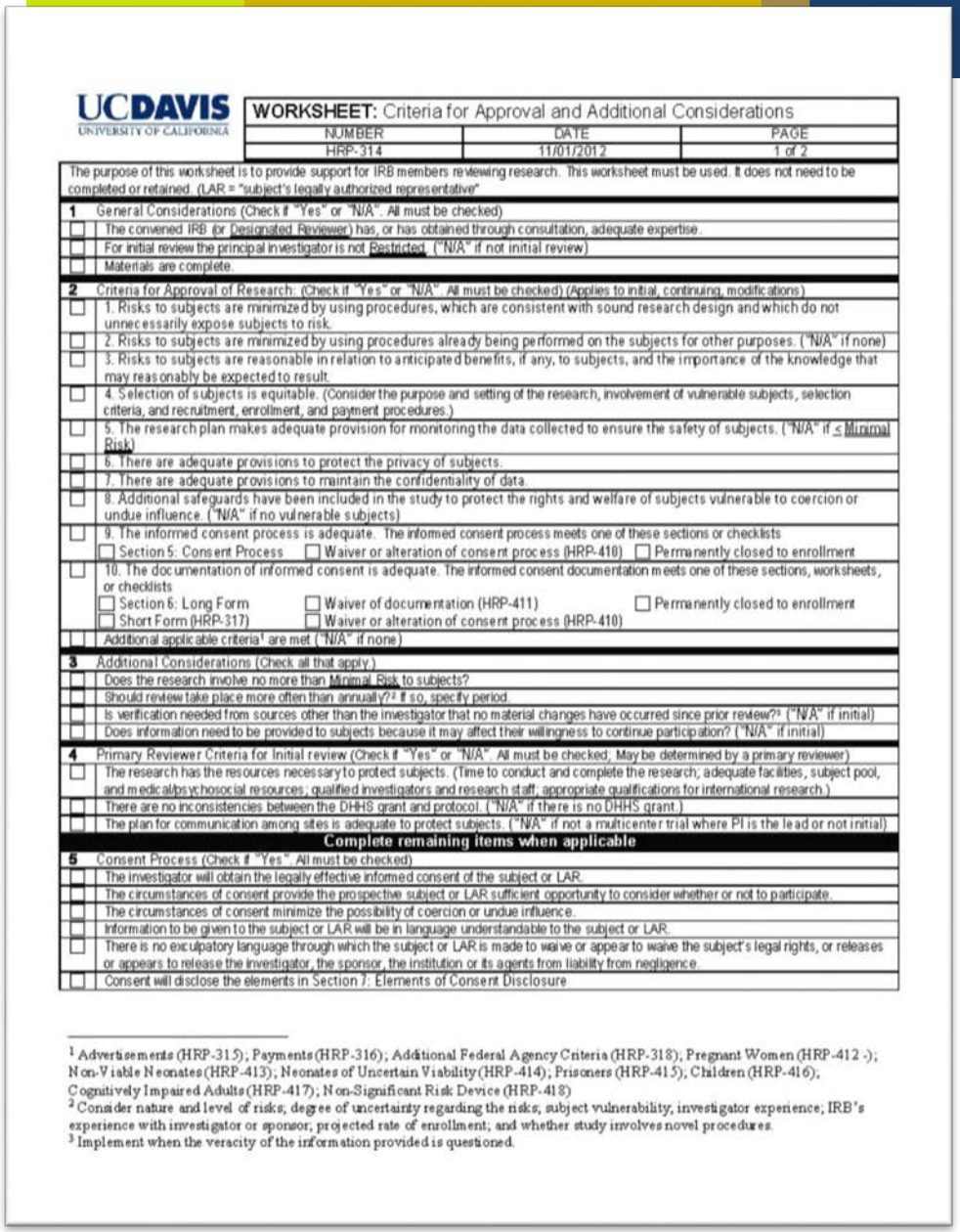
Don't miss the boat...

Common Reasons Why Initial Review of IRB Protocols May Be Delayed to Later Agendas:

- The submission is missing required ancillary approvals (RUC, CCSRC, SCRO, etc.)
- The protocol or HRP-503 is missing information needed for the IRB to make required determinations (e.g. subject recruitment, data monitoring for compliance and safety and protections for participant privacy and confidentiality)
- The consent form is missing, only the sponsor model consent is supplied, or the supplied consent does not contain information consistent with the UC Davis consent template.
- For studies involving devices, the investigator or sponsor does not provide sufficient information for an IDE Exemption, Non-Significant Risk or Significant Risk Determination and there is no evidence that an IDE has been obtained.
- A conflict of interest (COI) has been identified but no information about the COI is provided. The IRB must have sufficient information about the COI to make required determinations. This information is usually given to the IRB by providing the Forms 700U and 800.
- Sections of the electronic Initial Review Application Form are not completed or marked Not Applicable (N/A) when the section is applicable.
- For studies involving an investigational drug or biologic, the investigator brochure has not been provided; and for studies involving an approved drug, the investigational brochure or package insert is not provided.

UCDAVIS
OFFICE OF RESEARCH

Criteria of Approval, HRP-314



UCDAVIS
UNIVERSITY OF CALIFORNIA

WORKSHEET: Criteria for Approval and Additional Considerations

NUMBER	DATE	PAGE
HRP-314	11/01/2012	1 of 2

The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = "subject's legally authorized representative"

1 General Considerations (Check if "Yes" or "N/A". All must be checked)

- ☐ The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.
- ☐ For initial review the principal investigator is not Restricted. ("N/A" if not initial review)
- ☐ Materials are complete.

2 Criteria for Approval of Research: (Check if "Yes" or "N/A". All must be checked) (Applies to initial, continuing, modifications)

- ☐ 1. Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- ☐ 2. Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes. ("N/A" if none)
- ☐ 3. 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.
- ☐ 4. Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)
- ☐ 5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. ("N/A" if ≤ Minimal Risk)
- ☐ 6. There are adequate provisions to protect the privacy of subjects.
- ☐ 7. There are adequate provisions to maintain the confidentiality of data.
- ☐ 8. Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. ("N/A" if no vulnerable subjects)
- ☐ 9. The informed consent process is adequate. The informed consent process meets one of these sections or checklists
  - ☐ Section 5: Consent Process ☐ Waiver or alteration of consent process (HRP-410) ☐ Permanently closed to enrollment
- ☐ 10. The documentation of informed consent is adequate. The informed consent documentation meets one of these sections, worksheets, or checklists
  - ☐ Section 6: Long Form ☐ Waiver of documentation (HRP-411) ☐ Permanently closed to enrollment
  - ☐ Short Form (HRP-317) ☐ Waiver or alteration of consent process (HRP-410)
- ☐ Additional applicable criteria[1] are met ("N/A" if none)

3 Additional Considerations (Check all that apply.)

- ☐ Does the research involve no more than Minimal Risk to subjects?
- ☐ Should review take place more often than annually?[2] If so, specify period.
- ☐ Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[3] ("N/A" if initial)
- ☐ Does information need to be provided to subjects because it may affect their willingness to continue participation? ("N/A" if initial)

4 Primary Reviewer Criteria for Initial review (Check if "Yes" or "N/A". All must be checked; May be determined by a primary reviewer)

- ☐ The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)
- ☐ There are no inconsistencies between the DHHS grant and protocol. ("N/A" if there is no DHHS grant.)
- ☐ The plan for communication among sites is adequate to protect subjects. ("N/A" if not a multicenter trial where PI is the lead or not initial)

Complete remaining items when applicable

5 Consent Process (Check if "Yes". All must be checked)

- ☐ The investigator will obtain the legally effective informed consent of the subject or LAR.
- ☐ The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
- ☐ The circumstances of consent minimize the possibility of coercion or undue influence.
- ☐ Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
- ☐ There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
- ☐ Consent will disclose the elements in Section 7: Elements of Consent Disclosure

[1] Advertisements (HRP-315); Payments (HRP-316); Additional Federal Agency Criteria (HRP-318); Pregnant Women (HRP-412 -); Non-Viable Neonates (HRP-413); Neonates of Uncertain Viability (HRP-414); Prisoners (HRP-415); Children (HRP-416); Cognitively Impaired Adults (HRP-417); Non-Significant Risk Device (HRP-418)
[2] Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB's experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.
[3] Implement when the veracity of the information provided is questioned.

UCDAVIS
OFFICE OF RESEARCH

UCDAVIS
OFFICE OF RESEARCH