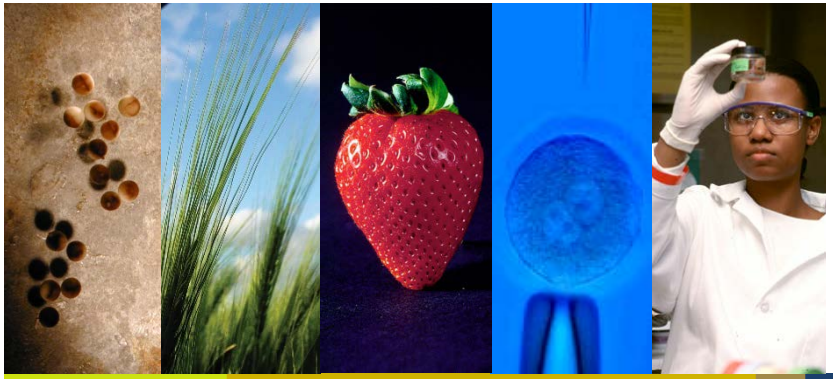

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Choosing Determinations for New Studies, Modifications, and Renewals

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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

Getting Started with Specific Determinations:

Topic	Specific Determinations
Criteria for Approval	Determine whether a submission meets the criteria of approval in HRP-314 Criteria of Approval and Additional Considerations: Yes/No
Risk Level	Minimal Risk or Greater than Minimal Risk *Minimal Risk means the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*
Financial Conflicts of Interest	Determine/Accept/Require Revisions to a Management Plan for Disclosed Financial Conflicts of Interest
Access and Use of Protected Health Information (PHI) under HIPAA	Waiver of HIPAA Authorization ("R" for recruitment only or "W" for full protocol). Researchers attest to the criteria for a waiver of HIPAA authorization in the Initial Review Application.

Checklists and Worksheets that help for Other Determinations:

Checklists required for determinations and protocol-specific findings include:

HRP 416 – Children
HRP 417 – Cognitively Impaired Adults
HRP 412 – Pregnant Women
HRP 413 – Non-viable Neonates
HRP 414 – Neonates of Uncertain Viability
HRP 415 – Prisoners
HRP 418 – Non-significant Risk Device
HRP 419 – Waiver of Consent for Emergency Research
HRP 410 – Waiver or Alteration of the Consent Process
HRP 411 – Waiver of Documentation of Consent

Worksheets that facilitate completeness of reviews include:

HRP 306 – Drugs
HRP 307 – Devices
HRP 315 – Advertisements
HRP 316 – Payments
HRP 317 – Short Form Consent
HRP 312 – Review of Information Items
HRP 322 – Emergency Use

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Specific Determinations for Research Involving Children, HRP-416:

Checklist	Specific Determinations
HRP 416 – Children, Risk	• Minors Risk Level 1 (minimal risk) • Minors Risk Level 2 (greater than minimal risk; direct benefit) • Minors Risk Level 3 (minor increase above minimal risk; indirect benefit; vital knowledge) • Minors Risk Level 4 (greater than minimal risk; not locally approvable; requires DHHS review) • Adequacy of Minor Assent Process (with attention to capacity)
HRP 416 – Children, Parent Signatures	• The IRB determines that permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. • The IRB determines that Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. (Cannot be selected for 21 CFR §50.53, 54/45 CFR §46.406, 407) • The IRB determines that parental permission is waived. (include waiver permission language)

The Question of Assent:

When minor's assent is appropriate,
will the IRB require and approve a process or a form?

An assent process may or may not involve a form; the process can be incorporated into a consent process and documented with standard UC Davis language and check-boxes

An assent form is separate from the study consent form, complementary to the consent, and prepared for the minor-aged research participant

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Additional Specific Determinations Regarding Children and Assent :

Checklist	Specific Determinations
HRP 416 – Children, Assent Not Required (21 CFR 50.55/45 CFR 46.408)	• The IRB determines that assent is not required because the children have limited capacity to understand. • The IRB determines that assent is not required because the protocol holds out a prospect of an important direct benefit to the child and is available only in the context of the research. • The IRB determines that assent is not required because the requirements for waiver of consent6 are met.
HRP 416 – Children, Assent Is Required	• The IRB determines that assent does not need to be documented. • The IRB determines that assent must be documented by having the child sign an IRB approved Information Sheet. • The IRB determines that assent must be documented on the consent form by the person obtaining assent. • The IRB determines that assent must be documented by having the child sign the consent document.
HRP 416 – Children, Assent Waived (45 CFR §46.408(a)/45 CFR §46.116(d)/21 CFR §50.55(d))	• The research involves no more than Minimal Risk to the subjects. • The waiver or alteration will not adversely affect the rights and welfare of the subjects. • The research could not practicably be carried out without the waiver or alteration • Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Determinations Regarding Cognitively Impaired Adults:

Checklist	Specific Determinations
HRP-417 Cognitively Impaired Adults	• *If funded or conducted by Department of Defense (DOD)*, the IRB determines the research is intended to be beneficial to the subjects. • The IRB determines: 1) aims of the research cannot be accomplished if the subjects were limited to adults capable of consent AND/OR 2) the research is intended to be beneficial to the subjects in a manner that is not available outside the research context. • The research involves no more than Minimal Risk to subjects. OR The research involves more than Minimal Risk to subjects, but the research holds out the prospect of direct benefit to the individual subjects. • Assent is required of subjects who are capable. • Documentation is required when the subject is capable. • Subjects will not be forced or coerced to participate.

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More Checklists & Determinations Regarding Other Vulnerable Populations:

Checklist	Specific Determinations
HRP 412 – Pregnant Women	Non-Federally Regulated, Minimal Risk Research: • The research is NOT funded or conducted by DHHS. • The research involves no more than Minimal Risk to pregnant women and fetuses. • The research is NOT funded or conducted by the Environmental Protection Agency (EPA). • The research results are NOT intended to be submitted to the Environmental Protection Agency (EPA).
HRP 413 – Non-viable Neonates	All 9 criteria on checklist must be satisfied and confirmed in the protocol. OR For research involving neonates that is not otherwise approvable and does not meet the requirements of 45 CFR 46.205, the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.
HRP 414 – Neonates of Uncertain Viability	All 5 criteria on checklist must be satisfied and confirmed in the protocol. OR For research involving neonates that is not otherwise approvable and does not meet the requirements of 45 CFR 46.205, the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

More Checklists & Determinations Regarding Other Vulnerable Populations:

Checklist	Specific Determinations
HRP-415 Prisoners	• For Non-DHHS-Regulated Research in which a subject becomes incarcerated, all 8 criteria on Part 1 of the checklist must be satisfied and confirmed in the protocol. • For research involving prisoners as subjects, the research must be consistent with one of the 5 categories (and supporting criteria) of the first section of Part 2 and all 9 additional criteria of checklist must be satisfied and confirmed in the protocol. • For research involving prisoners of the State of California or of a County or Local Jail in California, the research must pertain to either: 1) A drug or treatment available only through a treatment protocol or treatment IND, where the subject's physician has determined that access to that drug is in the best medical interest of the prisoner subject, OR 2) Behavioral research of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons which present minimal or no risk and no more than mere inconvenience to the prisoner subjects, And must satisfy the additional criteria of Part 3.

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