1. Background:
   1. Short description of background on experimental procedure(s)
   2. Short description of aims
2. Describe modification (you may refer to summary provided by site in documentation and describe them during the presentation.
3. Determine whether the criteria for approval are still met and document.
4. If the modification includes new risk information, list the new risks. Determine whether the risks need to be added to the consent document and whether any protocol revisions should be required to minimize the risk.
5. If the criteria for approval are no longer met, describe concerns.
6. Determine if the revisions affect any of the required additional determinations or revisions to previous additional determination.
7. If any new additional determinations or modifications to previous determinations are required, complete the appropriate checklist and/or review the appropriate worksheet.
   1. [HRP-416 Children;](http://research.ucdavis.edu/wp-content/uploads/HRP-416-CHECKLIST-Children.docx)
   2. [HRP-412 Pregnant Women](http://research.ucdavis.edu/wp-content/uploads/HRP-412-CHECKLIST-Pregnant-Women-1.docx)
   3. [HRP-417 Cognitively Impaired Adults](http://research.ucdavis.edu/wp-content/uploads/HRP-417-CHECKLIST-Cognitively-Impaired-Adults-1.docx)
   4. [HRP-413 Non-Viable Neonates](http://research.ucdavis.edu/wp-content/uploads/HRP-413-CHECKLIST-Non-Viable-Neonates-1.docx)
   5. [HRP-414 Neonates of Uncertain Viability](http://research.ucdavis.edu/wp-content/uploads/HRP-414-CHECKLIST-Neonates-of-Uncertain-Viability-1.docx)
   6. HRP-306 Drugs
   7. HRP-307 Devices
   8. HRP 418 Non-Significant Risk Device
   9. [HRP 318 Additional Federal Agency Criteria](http://research.ucdavis.edu/wp-content/uploads/HRP-318-WORKSHEET-Additional-Federal-Agency-Criteria-12.26.12-mm-1.docx)
   10. [HRP 410 Waiver or Alteration of the Consent Process](http://research.ucdavis.edu/wp-content/uploads/HRP-410-CHECKLIST-Waiver-or-Alteration-of-the-Consent-Process.docx)
   11. [HRP 411 Waiver of Written Documentation of Consent](http://research.ucdavis.edu/wp-content/uploads/HRP-411-CHECKLIST-Waiver-of-Written-Documentation-of-Consent.docx)
   12. [HRP 441 HIPAA Waiver of Authorization](http://research.ucdavis.edu/wp-content/uploads/HRP-441-CHECKLIST-HIPAA-Waiver-of-Authorization_cs-11.21.12-1.docx)
8. Make one of the following determinations:
   1. Approved
   2. Approved with administrative comments
   3. Modifications required
   4. Deferred
   5. Disapproved
9. List administrative comments, conditions, modifications required or reasons for deferral.
10. Determine whether enrollment should be halted pending approval of required modifications.
11. Document the recommended approval period. (See [HRP-319 Approval Period](http://research.ucdavis.edu/wp-content/uploads/HRP-319-WORKSHEET-Approval-Period-012017.docx))
12. Document risk level.

**Sample Review**

This study involves an investigational drug for \_\_\_\_\_\_\_\_. Background information supports this investigation.

Primary aim is to see if \_\_\_\_\_\_ is safe and effective for \_\_\_\_\_\_\_\_. Secondary aims are \_\_\_\_\_

Modifications include \_\_\_\_\_

Criteria for approval continue to be/are no longer met with the modification(s).

(If not met) \_\_\_\_\_\_is no longer met because \_\_\_\_\_\_\_\_\_

This modification does/does not affect the following additional determinations: \_\_\_\_\_\_\_\_\_\_\_\_

(If not met) \_\_\_\_\_\_\_\_ is no longer met because:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I recommend this approval/approval with administrative comments/modifications required/deferral.

Enrollment should/should not be halted pending approval of required modifications.

The following issues need to be addressed: