1. Background:
   1. Short description of background on experimental procedure(s)
   2. Short description of aims
2. Risks & Benefits: *(Criterion 1-3)*
3. General description of risks
4. Risk must be minimized - List revisions that would minimize risks, if any
5. Is risk/benefit ratio acceptable?
6. Subject Selection: *(Criteria 4)*
7. Is subject selection equitable?
8. Are vulnerable subjects being targeted/included? If yes, consider the following:
   * 1. Is inclusion of the vulnerable subjects necessary to answer the research question?
     2. Is there a prospect of direct benefit to the vulnerable subjects?
     3. Will knowledge gained from the research likely be important to other individuals with the vulnerable subjects’ condition?
     4. Complete applicable checklist [HRP-416 Children;](http://research.ucdavis.edu/wp-content/uploads/HRP-416-CHECKLIST-Children.docx) [HRP-412 Pregnant Women](http://research.ucdavis.edu/wp-content/uploads/HRP-412-CHECKLIST-Pregnant-Women-1.docx);

[HRP-417 Cognitively Impaired Adults](http://research.ucdavis.edu/wp-content/uploads/HRP-417-CHECKLIST-Cognitively-Impaired-Adults-1.docx); [HRP-413 Non-Viable Neonates](http://research.ucdavis.edu/wp-content/uploads/HRP-413-CHECKLIST-Non-Viable-Neonates-1.docx); [HRP-414 Neonates of Uncertain Viability](http://research.ucdavis.edu/wp-content/uploads/HRP-414-CHECKLIST-Neonates-of-Uncertain-Viability-1.docx)

1. If vulnerable subjects are targeted/included (*Criteria 8*), what provisions are included to minimize the risks of coercion and/or undue influence? (e.g. assent process; LAR)
2. Is the Data Monitoring Plan adequate? (Criteria 5) Required for research involving > minimal risk
3. Does the protocol include a data safety monitoring plan? (If no, revision is necessary)
4. Is the data safety monitoring plan acceptable? Must include:
   * 1. Name of person or entity responsible for monitoring the study
     2. Procedures to monitor subject safety and data accuracy
     3. Frequency of monitoring and review
     4. Anticipated adverse events
     5. Plan for reporting adverse events.
5. Privacy & Confidentiality: (Criteria 6 & 7)
   1. Are there adequate provisions to protect participant privacy? If no, make a recommendation.
   2. Are there adequate provisions to maintain the confidentiality of data? If no, make a recommendation.
   3. If waiver of patient authorization to use/disclose PHI for the purposes of research recruitment only is requested, recommend waiver approval if criteria are met.
6. Consent Process (Criterion 9)
   1. If waiver of consent is not requested:
      1. Is the consent process compliant with [HRP-090](http://research.ucdavis.edu/wp-content/uploads/HRP-090-SOP-Informed-Consent-Process-for-Research-2.docx) and [HRP 314](http://research.ucdavis.edu/wp-content/uploads/HRP-314-WORKSHEET-Reviewer-Advice-KS_11.01.12-1.docx)? If no, make a recommendation.
      2. Is the consent document understandable?
         1. If the consent document is not understandable, make recommendations for revisions.
      3. Are there any other concerns with the consent process (e.g. insufficient time to obtain effective consent)
   2. If waiver of consent is requested, complete [HRP- 410.](http://research.ucdavis.edu/wp-content/uploads/HRP-410-CHECKLIST-Waiver-or-Alteration-of-the-Consent-Process.docx)
7. Documentation of Consent (Signature on Consent Document) (Criterion 10)
   1. If waiver of documentation of consent is not requested:
      1. Is the consent process compliant with [HRP 091](http://research.ucdavis.edu/wp-content/uploads/HRP-091-SOP-Written-Documentation-of-Consent-2.docx)? If no, make a recommendation.
      2. Will the research likely include individuals who cannot read? If yes, Impartial Witness Signature Block should be included.
      3. Will research include individuals who cannot consent for themselves? If yes, Signature Block for Parental Permission or LAR should be included.
   2. If waiver of documentation of consent is requested, complete [HRP-411 Waiver of Written Document of Consent.](http://research.ucdavis.edu/wp-content/uploads/HRP-411-CHECKLIST-Waiver-of-Written-Documentation-of-Consent.docx)
8. Does the research involve a clinical investigation of an investigational drug, biologic or dietary supplement? If yes, review worksheet [HRP-306 Drugs](http://research.ucdavis.edu/wp-content/uploads/HRP-306-WORKSHEET-Drugs-07.22.13-1.doc)
9. Does the research involve a clinical investigation of a device? If yes, review worksheet [HRP-307](http://research.ucdavis.edu/wp-content/uploads/HRP-307-WORKSHEET-Devices-1.docx) Devices and complete [HRP-418 Non-Significant Risk Device](http://research.ucdavis.edu/wp-content/uploads/HRP-418-CHECKLIST-Non-Significant-Risk-Device.docx)
10. Scientific Validity - The protocol is scientifically valid and employs research procedures which are consistent with sound research design, in accordance with [HRP 320 SCIENTIFIC OR SCHOLARLY REVIEW](http://research.ucdavis.edu/wp-content/uploads/HRP-320-WORKSHEET-Scientific-or-Scholarly-Review-1.docx)
11. If the research is federally funded, is the protocol consistent with the grant proposal?
12. Make one of the following determinations:
    1. Approved
    2. Approved with administrative comments
    3. Modifications required
    4. Deferred
    5. Disapprove
13. List administrative comments, conditions, modifications required or reasons for deferral.
14. Document the recommended approval period. (See [HRP-319 Approval Period](http://research.ucdavis.edu/wp-content/uploads/HRP-319-WORKSHEET-Approval-Period-012017.docx))
15. 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 \_\_\_\_\_

Risks include: \_\_\_

Risk are minimized or Risks would be minimized if the following revisions are made: \_\_\_\_\_\_\_\_.

This study involves greater than minimal risk and the risk/benefit ratio is acceptable.

Subject Selection is equitable. (Or subject selection is not acceptable. The following subjects should be included/excluded: \_\_\_\_\_\_\_\_\_\_\_)

Children are included and the inclusion is necessary. Category \_\_, \_\_\_ Parent(s). See Checklist.

Cognitively impaired adults are included. The inclusion is not/is not necessary. There is/is not a prospect of direct benefit that is not otherwise available to these subjects, so inclusion is acceptable/unacceptable. See checklist.

Assent will/will not be required from the children and cognitively impaired adults, if they are capable. The Data Monitoring Plan includes/does not include a DSMB, and data safety monitoring plan is acceptable/unacceptable/incomplete. (The following is required\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

Provisions for privacy & confidentiality of data are acceptable or Provisions for privacy are acceptable but the following provisions for confidentiality are required:\_\_\_\_\_\_\_\_\_\_)

Consent Process is acceptable if revisions to the consent document are made. See attached redline consent document.

Procedures for Documentation of consent are acceptable.

This is clinical investigation of \_\_\_\_\_ . There is/isn’t an IND. This is acceptable/unacceptable. See worksheet.

The protocol is scientifically valid and employs research procedures which are consistent with sound research design.

This is a federally funded study and the protocol is consistent with the grant proposal.

The UC Davis investigator is the Lead PI and the Communication Plan with the relying sites is acceptable/unacceptable.

Concerns that need to be addressed: