1. Risks & Benefits: *(Criterion 1-3)*
2. General description of risks
3. Risk must be minimized - List revisions that would minimize risks, if any
4. Is risk/benefit ratio acceptable?
5. Subject Selection: *(Criteria 4)*
6. Is subject selection equitable?
7. 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?
8. 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)
9. Is the data monitoring plan: (Criteria 5) (Required for research involving > minimal risk) adequate.
10. 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.
11. 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)
			1. If there are concerns with the process, make recommendations
12. Documentation of Consent (Signature on Consent Document) (Criterion 10)
	1. If waiver of documentation of consent is not requested:
		1. Is the consent documentation 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, an 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.
		4. Will the research include participants who cannot understand or read English? If yes, require a translated consent document and interpreter.
13. Make one of the following determinations:
	1. Approved
	2. Approved with administrative comments
	3. Modifications required
	4. Deferred
	5. Disapproved
14. List administrative comments, conditions, modifications required or reasons for deferral.
15. Document the recommended approval period. (See [HRP-319 Approval Period](http://research.ucdavis.edu/wp-content/uploads/HRP-319-WORKSHEET-Approval-Period-012017.docx))
16. Document risk level

**Sample Review**

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

The criteria for approval are met/are not met.

The consent process and document are/are not adequate.

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

List administrative comments and/or conditions/modifications required/reasons for deferral.

Approval Period \_\_\_\_\_\_\_\_\_\_\_\_\_\_

At risk/minimal risk

The following issues need to be addressed: