CRITERIA REQUIRED BY FEDERAL REGULATIONS FOR IRB APPROVAL OF A HUMAN RESEARCH STUDY

		YES	NO
1	**RISKS TO SUBJECTS ARE MINIMIZED** ▪ Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk. ▪ Study utilizes procedures already performed for diagnosis/treatment -- when appropriate.	☐	☐
2	**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**	☐	☐
3	**SELECTION OF SUBJECTS IS EQUITABLE** ▪ Inclusion/exclusion criteria are adequate ▪ Research purpose and setting are appropriate ▪ Recruitment process is fair ▪ Special Requirements for vulnerable populations are addressed	☐	☐
4	**INFORMED CONSENT WILL BE SOUGHT OR WAIVED IN ACCORDANCE WITH 45 CFR 46.116— AND 21 CFR 50.25 FOR FDA-REGULATED RESEARCH**	☐	☐
5	**INFORMED CONSENT WILL BE DOCUMENTED OR DOCUMENTATION WAIVED IN ACCORDANCE WITH 45 CFR 46.117—AND 21 CFR 50.27 FOR FDA-REGULATED RESEARCH**	☐	☐
6	**PROVISIONS FOR MONITORING COLLECTED DATA ARE ADEQUATE TO ENSURE THE SAFETY OF SUBJECTS – WHEN APPROPRIATE.**	☐	☐
7	**PROVISIONS TO PROTECT PRIVACY OF SUBJECTS ARE ADEQUATE – WHEN APPROPRIATE.**	☐	☐
8	**PROVISIONS TO MAINTAIN CONFIDENTIALITY OF DATA ARE ADEQUATE – WHEN APPROPRIATE.**	☐	☐
9	**VULNERABLE POPULATIONS ARE ADEQUATELY PROTECTED FROM COERCION OR UNDUE INFLUENCE BY ADDITIONAL SAFEGUARDS.** Including but not limited to: protecting children, prisoners, educationally and/or economically disadvantaged, decisionally-impaired, incapacitated.	☐	☐
10	**IF MULTI-SITE RESEARCH STUDY MANAGEMENT OF INFORMATION RELEVANT TO PROTECTION OF SUBJECTS IS ADEQUATE.**	☐	☐
11	**FOR CONTINUING REVIEW OR REVIEW OF MODIFICATIONS, NEW INFORMATION THAT MIGHT AFFECT THE WILLINGNESS OF PARTICIPANTS TO CONTINUE TO PARTICIPATE WILL BE PROVIDED – WHEN APPROPRIATE.**	☐	☐
12	**FREQUENCY OF REVIEW**	☐ **12 MONTHS**	☐ **LESS: DETERMINE APPROPRIATE APPROVAL PERIOD:** ☐ **QUALIFIES FOR NO CONTINUING REVIEW**	

Important Notes:

- The study cannot be approved unless the IRB determines the study meets the above criteria.
- If substantive clarifications or modifications are needed before a Full Committee application can satisfy the criteria, the outcome of the review should be “D. Deferred.” The response will be returned to the Full Committee for Review.
- Additional criteria apply for a) waiving or altering consent or b) protecting vulnerable populations.