**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 by additional safeguards.**  See criteria for protecting children, prisoners, pregnant women, fetuses, and neonates. | | |  |  |
| **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:** |

**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.