Worksheet 306 – Primary Reviewer Supplemental Worksheet FDA Studies

1. **Drugs and Devices**
☐ A. The status of the drugs is adequately described [investigational, new use of an FDA-approved drug, or an FDA-approved drug for an approved indication]. ☐ B. The drug dose and route of administration are described and appropriate. ☐ C. Drug or device safety and efficacy data is sufficient to warrant the proposed testing. ☐ D. The *significant risk* or *non-significant risk* status of the device is described, and you agree with this determination. ☐ E. The protocol describes acceptable accountability, storage, access, and control of the devices.
Comments:
2. Recruitment
Advertisements for the study ☐ make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are consistent with FDA labeling regulations (i.e., advertisements state that the drug, biologic, or device is investigational; advertisements do not claim that the drug, biologic, or device is safe or effective for the purposes for which it is being investigated; ☐ explain that the test article is investigational when using terms, such as "new treatment," "new medication," or "new drug"; and ☐ do not allow compensation for participation to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
3. Informed Consent
☐ There is a statement in the consent document noting the possibility that FDA may inspect the records. ☐ There is a statement that the intervention was investigational and not approved by the FDA. ☐ There is a statement with regard to the unknown risks to pregnant women and fetuses. ☐ There is a description of the clinical trial website, http://www.clinicaltrials.gov, which at most includes a summary of research results but not any identifying information on the participant, and which the participant can access at any time. ☐ Unless documentation of informed consent is otherwise waived by the IRB, the participant or the LAR will sign and date the consent document. ☐ **Data Retention After Withdrawal**. The consent document complies with the following about data retention when participants withdraw from the clinical trial: • Data collected will remain part of the study database and will not be removed and the consent document does not give the participant an option to have data removed;

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The investigator may ask the withdrawing participant whether the participant wishes to provide continued follow-up; the investigator will distinguish, in the consent document or the consent process, study-related interventions and continued follow-up, and address the maintenance of privacy and confidentiality of the participant's information;

- The investigator will obtain consent with a consent document approved by the IRB before conducting the continued follow-up; and
- If the participant does not consent to the continued follow-up, the investigator will not access the participant's confidential records, such as medical records, but may review study data and consult public records.

☐ **Research Involving Children**. The research does not allow waiver or alteration of parental permission.