Investigational Drug Brochure (IDB) and Package Insert Decision Tree  
Version Date: July 8, 2013

Does this study involve testing or evaluating a drug or drugs?  

Yes

Do any of the drugs being tested or evaluated as part of this research study require an IND?

Yes

Provide the IRB with a copy of the package inserts for all of the drugs being tested and evaluated as part of the research study at the time of initial review. Any future changes to the package inserts relevant to the drug(s) as evaluated or tested in this study should be provided to the IRB as New Information Reports, if no changes to the IRB application or other IRB-approved materials are required, or as a change of protocol, if revisions to the IRB application or other IRB-approved materials are required.

No

STOP HERE. This decision tree does not apply to the research study.

No

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1) For drugs being tested or evaluated under an IND, provide the IRB with IDBs for these drugs at the time of initial review. Any future changes to the IDBs should be submitted to the IRB in accordance with the Guidance for Submission of IDBs at https://kb.wisc.edu/hsirbs/page.php?id=19254.

2) If any drugs being tested or evaluated for the study are FDA-approved and no IND is required, provide the IRB with package insert(s) for these drugs. Any future changes to the package inserts relevant to the drug(s) as evaluated or tested in this study should be provided to the IRB as New Information Reports, if no changes to the IRB application or other IRB-approved materials are required, or as a change of protocol, if revisions to the IRB application or other IRB-approved materials are required.