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?

No

Provide the IRB with package inserts at the time of initial review. Any future updates to package inserts should be provided to the IRB at continuing review, if the updates do not require changes to the IRB application or other IRB-approved materials, OR as a change of protocol, if revisions to the IRB application or other IRB-approved materials are required per this guidance.

Yes

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

Provide the IRB with IDBs at the time of initial review. Any future updates to IDBs should be provided to the IRB at continuing review, if the updates do not require changes to the IRB application or other IRB-approved materials, OR as a change of protocol, if revisions to the IRB application or other IRB-approved materials are required per this guidance.