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Reviewer Checklist - IND Determination for Investigational Drugs

Investigational New Drug means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of 21 CFR Part 312.

Please see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312> for further information on IND regulations.

If you answer "TRUE" to all of the following statements, an IND is NOT required.

- ☐ True ☒ False [Clear](#) The drug being used in the research is lawfully marketed in the United States.
- ☐ True ☒ False [Clear](#) The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.
- ☐ True ☒ False [Clear](#) The research is not intended to support a significant change in the advertising for the product.
- ☐ True ☒ False [Clear](#) The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- ☐ True ☒ False [Clear](#) The research is conducted in compliance with FDA requirements for IRB review and informed consent.
- ☐ True ☒ False [Clear](#) Based upon the protocol, the sponsor or investigator will not commercially distribute or test market the drug, as described in [21 CFR 312.7\(b\)](#).
- ☐ True ☒ False [Clear](#) The investigation is conducted in compliance with the requirements of 21 CFR 312.7, i.e., the drug may not be represented as safe or effective for any purposes for which it is under investigation, nor may it be commercially distributed or sold.

Final IND Determination:

- ☐ It is determined that this study requires an IND.
- ☐ It is determined that this study meets the federal requirements and does NOT require an IND.
- [Clear](#)

Comments and Revisions:

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