Purpose: This checklist can be used to help investigators determine whether US Investigational New Drug (IND) regulations apply to their research project.

Audience/User: Clinical Investigators, site study coordinators

Details: The criteria listed here are specified in IND regulations at 21 CFR 312.2(b).

Best Practice Recommendations and Notes:

- Complete this checklist during protocol development and retain the checklist for documentation. For studies that DO involve drugs[1] and for which an IND is NOT being pursued, consider including the completed signed checklist in the IRB submission.
- Use the "Explain" field to provide detailed rationale for items where "No" is selected, especially in STEP 2, Item 4.
- **Consult the (draft) FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs)— Determining Whether Human Research Studies Can Be Conducted Without an IND for further details, including examples of rare instances where INDs do or do not apply.**

STEP 1: Mark "Yes" or "No" for each of the below:

Yes	No		
☐	☐	1.	Does the project involve administration of a drug to humans? A drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."
☐	☐	2.	Is the project a clinical investigation? A clinical investigation is an experiment in which a drug is administered to humans for any use that is not per the marketed use of the drug in the course of medical practice. If use of the drug is subject to a randomization scheme, the project is a clinical investigation.

If only one of the above rows is checked "Yes", stop; the study does not require an IND. Otherwise, proceed.

STEP 2: Is the clinical investigation exempt from IND Regulations?

☐ **21 CFR 312.2(b)(1) To be exempt under this category, <u>all</u> of these sub-requirements must apply:**

1. The clinical investigation involves a drug product lawfully marketed in the U.S.	☐Yes
2. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use and is not intended to be used to support any other significant change in the labeling for the drug	☐Yes
3. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product	☐Yes
4. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. If oncologic therapy and IND is not necessary to permit deviations from the approved labeling to the extent that such changes are supported by the scientific literature and generally known clinical experience. Please provide justification:	☐Yes
5. The investigation is conducted in compliance with the requirements for IRB review set forth in21 CFR Part 56 and with the requirements for informed consent set forth in 21 CFR Part 50	☐Yes
6. The investigation is conducted in compliance with 21 CFR 312.7 (regarding promotion and charging for investigational drugs)	☐Yes

☐ **21 CFR 312.2(b)(2) To be exempt under this category, <u>all</u> of these sub-requirements must apply:**

1. The clinical investigation involves one of the following in vitro diagnostic biological products (at least one box should be checked)	☐blood grouping serum ☐reagent red blood cells ☐anti-human globulin
2. The product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure	☐Yes
3. The product is shipped in accordance with 21 CFR Part 312.160	☐Yes

☐ **21 CFR 312.2(b)(3) To be exempt under this category, this sub-requirement must apply:**

1. The investigation involves a drug intended solely for tests in vitro or in laboratory research animals **and** the drug is shipped in accordance with 21 CFR 312.160	☐Yes

☐ **21 CFR 312.2(b)(5) To be exempt under this category, this sub-requirement must apply:**

1. The clinical investigation involves a placebo **and** the investigation does not otherwise require submission of an IND (refer to the sections above)	☐Yes

Final determination: the project does ☐ / does not ☐ require an IND

_____ _____

Sponsor/Investigator Signature **Date**