



IND EXEMPTION CRITERIA

Federal Research Regulations

The FDA is responsible for regulating drugs for human use. Investigators conducting clinical trials involving drugs have specific responsibilities outlined in 21 CFR 312, Subpart D – Responsibilities of Sponsors and Investigators.

This checklist will assist investigators in determining if an IND is needed from the FDA in order to conduct a clinical trial using a drug or biologic. The IRB may determine that an IND is not necessary based on the criteria below. However, the IRB may also require that the investigator request and exemption from the FDA, which requires the submission of an IND application.

A clinical investigation that uses a placebo does not require an IND if exemption criteria below are met.

Exemption Criteria for Drugs and Biologics that are Currently FDA Approved

According to 21 CFR 312.2(b)(1), if a drug product is FDA approved, it may be used in a clinical investigation without an IND if **all** of the following criteria are met:

- i. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- ii. 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.
- iii. 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.
- iv. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50. This means that an exception from informed consent for emergency research will not be invoked.
- v. The investigation is conducted in compliance with the requirements of 312.7. This means that the sponsor or investigator will not commercially distribute or test market the drug according to an unapproved indication.

Exemption Criteria for *in vitro* Diagnostic Biological Products

According to 21 CFR 312.2(b)(2), an *in vitro* diagnostic biological product may be used in a clinical investigation without an IND if **all** of the following criteria are met:

- i. The product under study is used in a diagnostic procedure that will also be confirmed with another, medical established diagnostic product or procedure.
- ii. The product is shipped in compliance with 312.160.
- iii. The product is one of the following:
 - a. Blood grouping serum
 - b. Reagent red blood cells
 - c. Anti-human globulin

References & Links

*IRB SOP 502: Clinical Research
Involving Investigational
Drugs and Devices*

<http://www.research.utah.edu/irb/guidelines/sop.html>

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



*ICH E6: Good Clinical Practice:
Consolidated Guidance (see
page 13 for the list of
Investigator Responsibilities)*

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>

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