Research Involving Drugs or Biological Drug Products (IRB HRPP 4.1 & 4.2)

JUNE 2025 CONTINUING EDUCATION

Any study involving a drug, whether FDA approved or not - requires IRB review and approval!

eIRB Application

Drugs/Chemicals/Substances

Drugs, chemicals, metabolites, nutritional substances, biological agents or other substances whether regulated or not by the Food & Drug Administration (FDA) that will be administered to subjects

☐ Use of Placebos

- The PI indicates in the eIRB application that drugs will be used in the research study and includes (if applicable):
  - IND/IND Exemption
  - CV
  - Current/supporting literature
    - Applicable if: Use of the marketed drug(s) is a manner not currently approved by the FDA, but does not significantly increase risk to the subjects
  - Investigator's Brochure
  - Protocol
  - Informed Consent

Informed Consent Requirements:

- Purpose and background section must include:
  - Clear statement that the drug/biologic is investigational and has not been approved or, if studying an approved drug/biologic, that it is approved but not for the use being studied.
  - A brief lay description of what the drug/biologic is and how it is thought to act.
  - Must not state or imply that the issuance of an IND is an approval or endorsement by the FDA.
- Confidentiality Section must include:
  - A statement that the FDA may review subjects' medical records and research records which identify the subjects.
- Alternative section must include:
  - If studying an approved drug/biologic - must explain that subjects can receive drug/biologic without participating in the study.
    - An exception to this may be granted if the off-label prescription of the drug/biologic is unrealistic or unsafe outside of a carefully controlled clinical study.
- Cost section must include:
  - How the costs of the study drug/biologic, as well as the administration of the product will be covered.

IND Exemption(s):

21CFR 213.2(b) and 21 CFR 320.31

1. Drug/biologic is lawfully marketed in the United States, no intention of reporting to the FDA the changing the indication/labeling/advertising for the drug, does not increase risk associated with the use of the drug, etc.
2. in vitro diagnostic biological product and intended to confirm a diagnosis made by another diagnostic procedure
3. Intended solely for tests in in vitro or in lab research animals, shipped in accordance with FDA regulations
4. Clinical investigation using a placebo if the investigation does not otherwise require a submission of an IND
5. Clinical investigation involves an in vivo bioavailability or bioequivalence study (exceptions to this exception)

How to review:

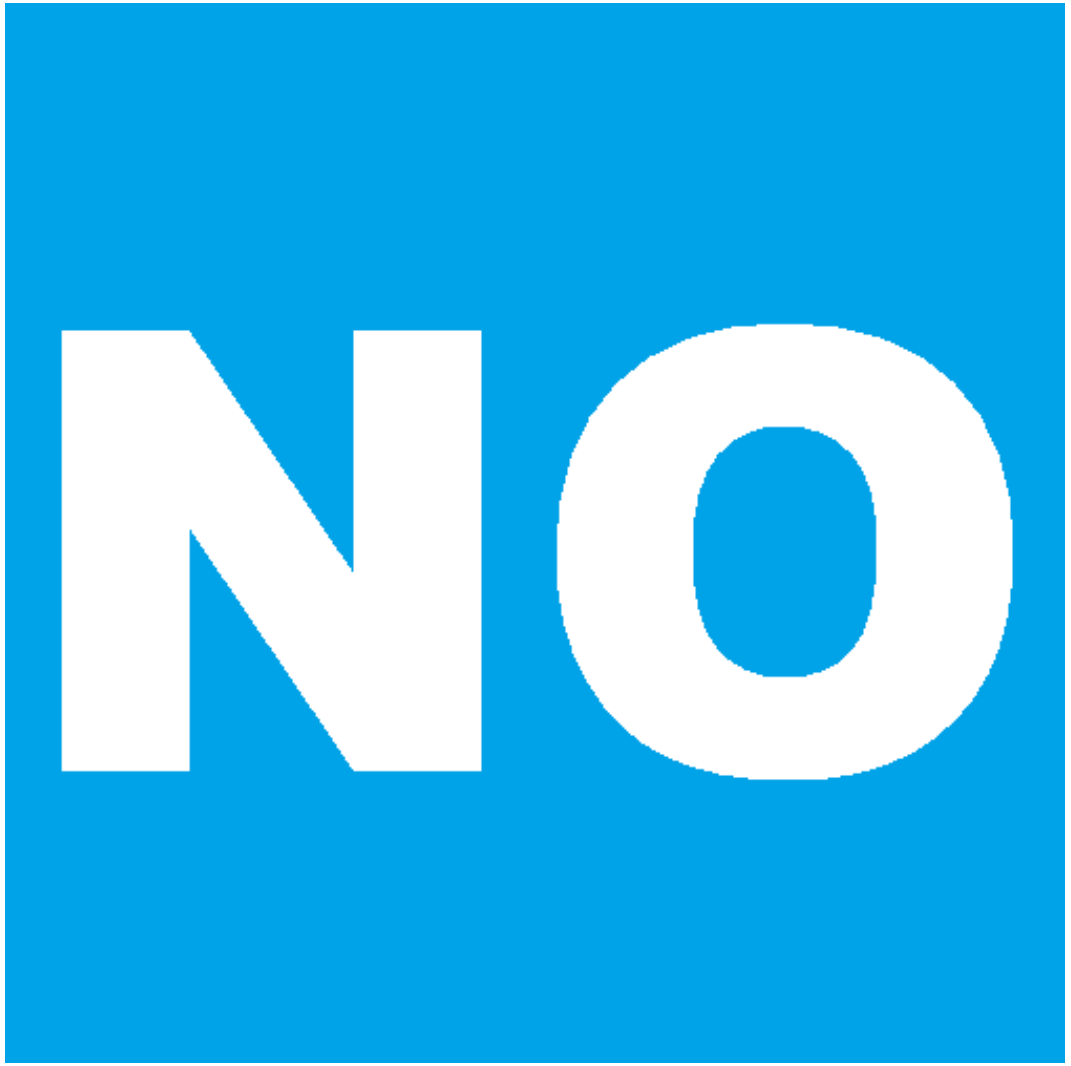
- IRB staff will review the application to confirm that there is an IND and that it is a valid IND number
  - Protocol Review
  - IND acknowledgement letter from the FDA
- One PharmD or MD IRB member will be assigned as a primary reviewer
- The IRB Chair may consult with the PharmD or MD IRB members prior to the convened meeting
  - Additional supporting literature may be requested
  - PI may be asked to attend the meeting to discuss the use of the drug(s)
- The Board will make the decision if the principal investigator must query the FDA regarding the need for an IND given the nature of the research and the drug(s) use.
  - Table
  - Approve with Contingency – approval will not be released until documentation from the FDA is received including IND number or that an IND is not required.

Is an IND needed?

EXAMPLE 1: An investigator proposes a small pilot study of an approved drug for a novel use and states that an IND is not needed because the data will not be submitted to the FDA. The investigator explains that if the pilot data looks promising a larger trial will be submitted with an IND.

Example 1

ANSWER: The IRB **is likely to approve** the pilot study without an IND because a small pilot study is an appropriate first step in determining whether a change in labeling should be sought.



Is an IND needed?

EXAMPLE 2: An investigator proposes a multi-center randomized trial of an approved drug for a novel use and states that an IND is not needed because the data will not be submitted to the FDA.

Example 2

ANSWER: The IRB **is not likely to approve** the study without an IND because the data could be important and should be considered by the FDA.

What questions do you have?