The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs. This worksheet is to be used. It does not need to be completed or retained.

1 Drug Applicability
- Does this protocol involve any use of a drug in a human other than the use of an approved drug in the course of medical practice? If "Yes," use the remainder of the worksheet; If "No," FDA drug regulations do not apply.

2 IND Requirements
- The drug has a valid IND. (Complete Sections 3 and 4)
- The drug is exempt from the IND requirements (Complete Section 5)

3 IND Validation
- Sponsor protocol imprinted with the IND number.
- Written communication from the sponsor documenting the IND number.
- Written communication from the FDA documenting the IND number. (Required if the investigator holds the IND.)

4 Drug Control
- The plan for storage, control, and dispensing of the drug is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent.

5 IND Exemptions

6 IND Oversight for investigators who hold the IND
- The investigator does NOT hold the IND.
- The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.
- An audit has documented that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).
### WORKSHEET: Drugs

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1. The term “drug” means
   - (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
   - (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
   - (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
   - (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

2. If there are questions about which category is appropriate, have the investigator apply for an IND following 21 CFR §312.23.

3. The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and Expiration Dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. The investigator must maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.