USC iStar

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17. Methods and Procedures - Drug and Biologic Information

This screen is required if you indicated the use of Approved or Invesigational Drugs and Biologics (Question 9.2.)

17.1. Fill in an entry for all drugs and biologics that will be administered in this study. *Guidance*

Add

Drug Name	FDA Approved	IND# or N/A	IND Holder	Supplied By

There are no items to display

17.2. Describe where the drugs/biologics will be stored, how they will be secured, and how the inventory will be managed. *Guidance*

17.3. Attach a copy of the Investigators Drug Brochure for each IND Agent and package insert for any other study medications. *Guidance*

Add

name	Version	Modified

There are no items to display

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Add 17-1 Drug

Add Drug/Biologic Entry

Please enter the fields below and click 'OK' when done.

17.1.1. * **Drug/Biologic Name:** *Guidance*

17.1.2 * **The FDA Investigational New Drug (IND) Status of the drug or biological:** *Guidance*
(An IND is a request for authorization from the Food and Drug Administration to administer an investigational drug or biological product to humans.)

- [x] **The drug/biologic has an IND**

as evidenced by:

IND Number:

IND Holder:

- [x] **The IND application has been submitted**

Enter the Date the IND application was submitted:

- [x] **The investigation is believed to be exempt from FDA regulations**

Permitted exemptions from the IND regulations:

- [x] **The clinical Investigation of a drug product that is lawfully marketed [21 CFR 312.2(b)(1)]:**
  - [ ] The drug is lawfully marketed in the U.S.
  - [ ] The research 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.
  - [ ] The research is not intended to support a significant change in the advertising for the product
  - [ ] The research 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.
  - [ ] The research is conducted in compliance with the marketing limitations described in 21CFR 312.7.

- [x] **The clinical investigation involves in vitro diagnostic biological products [21 CFR 312.2(b)(2)] where:**
  - [ ] The research involves one of the following: blood grouping serum, reagent red blood cells, or anti-human globulin.
  - [ ] The product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.

☐ The drug is shipped in accordance with 21 CFR 312.160.

☑ **The investigation involves a drug intended solely for tests in vitro or in laboratory research animals [21 CFR 312.2(b)(3)].**

☑ **The clinical investigation involves use of a placebo AND the investigation does not otherwise require submission of an IND [21 CFR 312.2(b)(5)].**

☑ **FDA determination of exemption. The research has been submitted to the FDA who determined in writing that an IND is not required.**

Attach correspondence with FDA determination:
[None] Add

17.1.3. * **FDA Approved for marketing for this indication?** *Guidance*

○ Yes ○ No Clear

17.1.4. * **Supplied By:** *Guidance*

* Required

OK | OK and Add Another | Cancel