USC iStar

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18. Methods and Procedures - Device Information

This screen is required if you indicated the use of Approved or Investigational Devices (Question 9.2.)

18.1. Fill in an entry for all devices that will be used in this study. *Guidance*

Add

Generic and Brand Names	Category of Regulation

There are no items to display

18.2. Attach a copy of any Investigators Device Brochures for the devices listed above. *Guidance*

Add

name	Version	Modified

There are no items to display

18.3. Describe where the investigational devices will be stored, how they will be secured, and how the inventory will be managed. *Guidance*

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Add 18-1 Device

Add New Device Entry

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

18.1.1. * Indicate the generic and brand names of the device. *Guidance*

18.1.2. (CHLA Only) Attach the requisition form for this device. *Guidance*
[None] Add

18.1.3. * Indicate the category of regulation for this device (select one). *Guidance*

- (•) The device is exempt from IDE regulations (answer question 18.1.4)
- ( ) The device has a humanitarian device exemption - HDE (answer question 18.1.5)
- ( ) The device qualifies for an abbreviated IDE - nonsignificant risk devices (answer question 18.1.6)
- ( ) The device requires an IDE - significant risk devices (answer question 18.1.7)

Clear

18.1.4. If the device is **exempt from the IDE regulations**, indicate the category of use. *Guidance*

- ( ) A legally marketed device when used in accordance with its labeling §812.2(c)(1,2).
- (•) A diagnostic device [all checkboxes in 18.1.4.a must be checked for this to apply].
- ( ) Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510 (k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ( ) The device is a custom device as defined in 21 CFR§812.3(b) unless the device is being used to determine safety or effectiveness for commercial distribution.

Clear

18.1.4.a. In order to qualify for exemption as a diagnostic device, all of the following must be true:

- [ ] The sponsor will comply with the labeling requirements in §809.10(c)
- [ ] The testing is noninvasive
- [ ] The testing does not require an invasive sampling procedure that presents significant risk
- [ ] The testing does not by design or intention introduce energy into a subject
- [ ] The testing is not used as a diagnostic procedure without conformation by another medically established diagnostic product or procedure

18.1.8. Name of IDE Holder: *Guidance*

* Required

OK | OK and Add Another | Cancel

Add 18-1 Device

Add New Device Entry

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

18.1.1. * Indicate the generic and brand names of the device. *Guidance*

18.1.2. (CHLA Only) Attach the requisition form for this device. *Guidance*
[None] Add

18.1.3. * Indicate the category of regulation for this device (select one). *Guidance*

- ( ) The device is exempt from IDE regulations (answer question 18.1.4)
- (•) The device has a humanitarian device exemption - HDE (answer question 18.1.5)
- ( ) The device qualifies for an abbreviated IDE - nonsignificant risk devices (answer question 18.1.6)
- ( ) The device requires an IDE - significant risk devices (answer question 18.1.7)

Clear

18.1.5. If the device has a **humanitarian device exemption (HDE)**, indicate the HDE number and attach the HUD document below. *Guidance*

18.1.5.1. Attach the HUD document.
[None] Add

18.1.8. Name of IDE Holder: *Guidance*

* Required

OK | OK and Add Another | Cancel

Add 18-1 Device

Add New Device Entry

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

18.1.1. * Indicate the generic and brand names of the device. *Guidance*

18.1.2. (CHLA Only) Attach the requisition form for this device. *Guidance*
[None] Add

18.1.3. * Indicate the category of regulation for this device (select one). *Guidance*

- ( ) The device is exempt from IDE regulations (answer question 18.1.4)
- ( ) The device has a humanitarian device exemption - HDE (answer question 18.1.5)
- (•) The device qualifies for an abbreviated IDE - nonsignificant risk devices (answer question 18.1.6)
- ( ) The device requires an IDE - significant risk devices (answer question 18.1.7)

Clear

18.1.6. If the device qualifies for an **abbreviated IDE (nonsignificant risk devices)**, the following must be true: *Guidance*

	Name
☐	The device is not a banned device
☐	The sponsor will comply with FDA requirements for monitoring the investigation (21 CFR 812.46).
☐	The investigator sponsor/investigator will comply with FDA requirements for records and reports (21 CFR 812.140, 21 CFR 812.150).
☐	The investigator will not market or promote this device (21 CFR 812.7).
☐	The sponsor ensures that each investigator participating in an investigation of the device obtains consent (21 CFR 50) from each subject under the investigator's care and documents it, unless documentation is waived.
☐	The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval

You must also attach documentation at 18.1.6.1 indicating that the device poses a nonsignificant risk (NSR) of harm to the study subjects from the sponsor with an explanation of its NSR determination and any other information that may assist the IRB in evaluating the risk of the study including:
-The sponsor should provide the IRB with a description of the device,
- reports of prior investigations with the device,
- the proposed investigational plan,
- a description of patient selection criteria and monitoring procedures,
- as well as any other information that the IRB deems necessary to make its decision.
- The sponsor should inform the IRB whether other IRBs have reviewed the proposed study and what determination was made.
- The sponsor must inform the IRB of the FDA's assessment of the device's risk if such an assessment has been made.

18.1.6.1. Attach documentation from the sponsor or investigator sponsor supporting the NSR opinion.

Add

name	Version	Modified

There are no items to display

18.1.8. Name of IDE Holder:

Guidance

* Required

OK | OK and Add Another | Cancel

Add 18-1 Device

Add New Device Entry

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

18.1.1. * Indicate the generic and brand names of the device. *Guidance*

18.1.2. (CHLA Only) Attach the requisition form for this device. *Guidance*
[None] Add

18.1.3. * Indicate the category of regulation for this device (select one). *Guidance*

- ○ The device is exempt from IDE regulations (answer question 18.1.4)
- ○ The device has a humanitarian device exemption - HDE (answer question 18.1.5)
- ○ The device qualifies for an abbreviated IDE - nonsignificant risk devices (answer question 18.1.6)
- ◉ The device requires an IDE - significant risk devices (answer question 18.1.7)

Clear

18.1.7. **IDE (significant risk device)** number**:** *Guidance*

18.1.7.1. Attach a copy of the FDA letter indicating approval.
[None] Add

18.1.8. Name of IDE Holder: *Guidance*

* Required

OK | OK and Add Another | Cancel