

Human Subjects Research Annual Disclosure

For studies that have an FCOI and management plan, annual disclosure is required. This ongoing reporting ensures that any changes in the financial relationship are appropriately managed by the existing management plan.

When an application for Continuing Review is submitted, the IRB will screen for an existing FCOI and management plan. If the study has an active management plan it will fit into one of the three categories below.

1. A Form 800 was submitted within 90 days of study expiration.
 - a. The IRB confirms the management plan is adequate and completes the continuing review.

2. The investigator has a previous positive Form 800.
 - a. The IRB analyst will generate a Form 800-IRB.
 - b. The investigator must confirm the information present in the Form 800-IRB and submit the disclosure via eCOI.
 - i. See screen shots of the investigator's process below.
 - c. The COIC will review the Form 800-IRB.
 - d. The IRB will confirm the management plan is adequate and complete the continuing review.

3. The investigator does not have a positive Form 800.
 - a. The investigator must submit a new Form 800.
 - b. The COIC will review the Form 800.
 - c. The IRB will confirm the management plan is adequate and complete the continuing review.

Human Subjects Research Annual Disclosure

Form 800-IRB

Demographics

Name

Jacob Jones

Email

jacjones@ucdavis.edu

Department

Project Details

Type of Proposal / Disclosure

IRB Annual update for continuing review (for investigators who previously submitted a positive Form 800)

Information on prior filing being updated:

Project: Jacob Jones' awesome project

Sponser: NIH Cooperative Human Tissue Network

IRB #: 1234567

Income SFI: none

Equity SFI: none

Prior IRB Update: Blah blah blah

Are there any changes or modifications to your existing SFI(s) (e.g. increase or decrease in value)?

- Yes
 No

If the investigator reported either income or equity SFI dollars, they would be displayed where it now says 'none.'

Human Subjects Research Annual Disclosure

Sign and submit

Verification

I acknowledge my responsibility to immediately disclose any new reportable financial interest obtained during the term of the project. I certify that this is a complete disclosure of my financial interests related to the proposed project/sponsor.

Signature

Cancel

Save Draft

Finalize

The investigator must sign and finalize the Form 800-IRB. The COIC will review the disclosure to ensure the management plan is adequate.