

eDisclose User Guide:

How to Update a Disclosure

Last Update	January 21, 2021
Intended Audience	Faculty Member/Owner of Disclosure
Purpose	To provide the user with step-by-step instructions on how to update a disclosure

Please first refer to the eDisclose Getting Started Guide before continuing.

NOTE: Only the Faculty Member/Owner of Disclosure can create and submit their own disclosure. COI staff can not initiate an original disclosure nor an update to an existing disclosure.

Follow the steps below to update a disclosure:

Step 1. Close all open web browsers

Step 2. Open a new browser and go to: <http://edisclose.jhu.edu>

Step 3. Login using your JHED ID and password

Step 4. Select the “My Disclosures” workspace link on the left-hand side navigation panel

Step 5. Select a disclosure from the workspace whose state is in “Review Complete”. To select a disclosure, click on the Disclosure ID which is hyperlinked. Clicking on this will take you to the Disclosure Workspace

NOTE: You are unable to edit or update a disclosure in the “Pending Review” section of this workspace. If you require an edit to a disclosure in this section, please email policy@jhmi.edu

Step 6. Select the “Update Disclosure” button on the left-hand side

The screenshot shows the eDisclose web application interface. At the top, there's a header with the Johns Hopkins University logo and the text 'eDisclose'. Below the header, there's a navigation bar with 'Dashboard' and 'Help Desk' links. The main content area is titled 'Disclosure Workspace'. On the left side, there's a sidebar with a 'Current Status' section showing 'Review Complete'. Below this, there are links for 'View Form', 'Print Disclosure', 'View Differences', 'Contact Staff', and 'Update Disclosure'. The 'Update Disclosure' button is circled in red. On the right side, there's a section for 'Owner: User SOM Tester' and 'Entity: PFIZER INC'. Below this, there's a 'Questions?' section with contact information. At the bottom, there's a 'Relationship Overview' table with columns for 'Outside Service' and 'Fiduciary/Founder Role'.

Outside Service	Fiduciary/Founder Role
Data Safety Monitoring Board	Board of Directors
Legal Consulting/medical-legal	Founder
Publishing/Editing/Authoring	Other
Speaking	
Teaching	
Accredited CME Program	
Other	

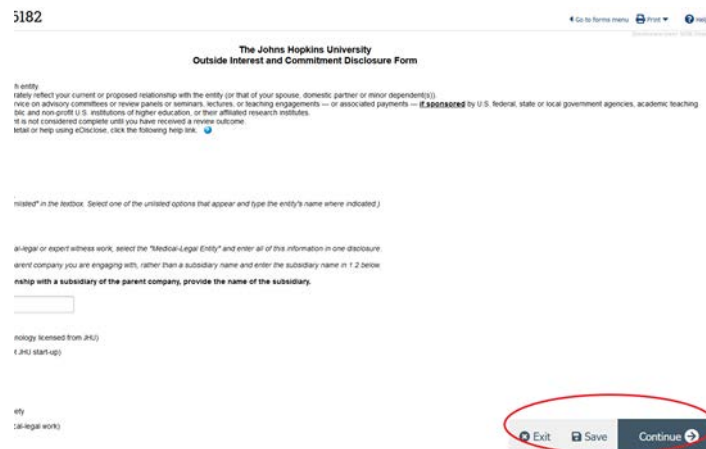
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Step 7. Begin revising your disclosure to best reflect your ongoing relationship.

Step 8. Select “Continue” to proceed through each SmartForm

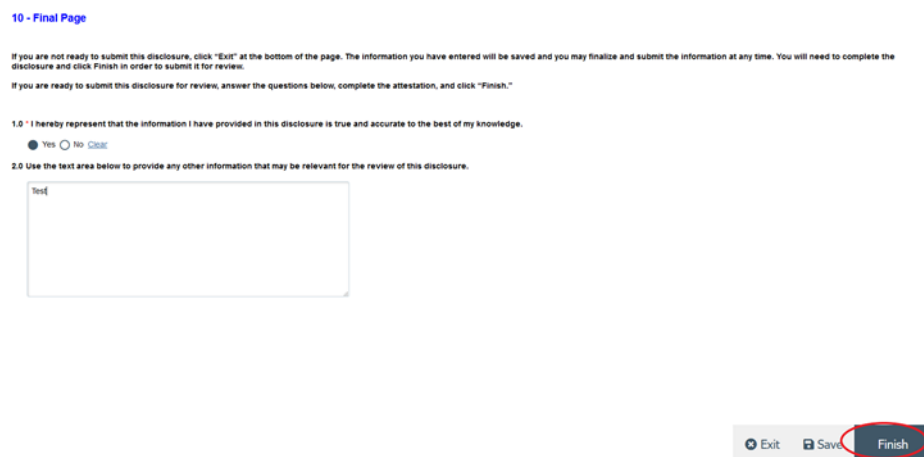
- All required fields are indicated with a *
- You can select “Save” at any time and exit the form



Step 9. Due to a system update, if you have previously indicated participating in research related to the entity you **MUST** reenter the data. See Step 12 for details.

Step 10. Proceed through all sections of the SmartForm until you arrive at the Final Page

Step 11. Select “Finish” on the last page of the Smart Form (Final Page). You will be automatically taken back to the Update workspace. If you receive errors upon selecting Finish, see Step 11a



Step 11a. If selecting “Finish” results in a note that says “Could not update the Transaction due to one or more errors” you will need to follow these steps. Please refer to the image below as a guide.

- Clear your response in question 1.0
- Select the “Validate” tab to review the error or warning messages

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- Select the section that the error is appearing in, and revise your response as necessary
- Select “Refresh” at the top of the error/warning messages to ensure the errors have been resolved

Once each section has a green check mark next to it, navigate again to the “Final” page and respond to question 1.0 and click “Finish”

The screenshot displays the eDisclose interface. On the left, a sidebar titled "Error/Warning Messages (6)" lists four sections: "1 - Relationship Overview" (green checkmark), "2 - Outside Services" (red minus sign), "3 - Fiduciary/Founder Roles" (green checkmark), and "4 - Licensed Technology" (green checkmark). The "2 - Outside Services" section is highlighted with a red circle and contains an error message: "Authorship ICMJE This is a required field; therefore, you must provide the required information." A "Refresh" button is circled in red at the top right of the sidebar. On the right, the main content area is titled "Editing: TR0001" and shows a red error message: "Could not update the Transaction Validation Failed: There are errors." Below this, the "10 - Final Page" is displayed, featuring a statement "1.0 * I hereby represent that" with "Yes" and "No" radio buttons and a "Clear" link. The "Yes" radio button is selected and circled in red.

Step 12. Updating Human Subjects Research and Non-Human Subjects Research:

- Due to a system update, you will be prompted to enter the details of the relationship between the entity and your research again
- You will be asked to enter each protocol or project individually
- The data that you previously entered is shown in a read-only format embedded in a blue text-box
- Using the information in that section, please use the “Add” button in question 1.0 to re-add each protocol or project that you participate in
- Clicking “Add” will open a pop-up window
- You will need to respond to the questions within the “Add” window on a per protocol basis

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8 - Human Subjects Research

The questions below relate to Human Subject Research protocols in which you participate or propose to participate, e.g., as an investigator or study team member ("related Subjects Research") entry for each individual protocol for which any of the following applies to your research:

- Entity provides financial support for the study.
- Entity provides non-financial material support for the research.
- Entity develops or sells products or technology(ies) evaluated or used in the study.
- Entity has licensed technology you invented – whether or not the technology is used in the research.

1.0 * Click 'Add' to add Human Subjects Research protocols in which you participate that are related to this entity.

+ Add

CLICK HERE TO RE-ENTER RESEARCH OR ADD NEW RESEARCH

IRB #	Title	Principal Investigator	IRB Status	Additional Info
There are no items to display				

Note: Your previous responses to the following questions are displayed below as read-only information. Due to a system update, you will be prompted to enter this information entered information about the protocol in your previous disclosures for the entity. For additional details, refer to the User Guides included under the Help Desk tab of this policy@hmc.edu.

• Does the entity manufacture devices, drugs or technology used in your human subjects research?

Yes

Comments:

ReconstratA has contracted a third party manufacturing company to produce the first prototype to be tested in humans. The device will be mostly made of stainless steel and all com the device base.

READ ONLY DATA

• Does the entity provide material support for your human subjects research?

Yes

Comments:

ReconstratA will provide the blades for the devices. Blades will be disposable but also autoclavable, in case multiple use will be deemed appropriate by the surgeon.

• Does your human subjects research involve technology you invented that was licensed to the entity?