



Applications for Research Compliance PORTAL

## eCOI Disclosure Manual

This guide serves to aid in creating and submitting conflict of interest disclosures.

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## Welcome to ARC

Our on-line ARC system streamlines the process of submitting, approving, tracking, and managing eIRB eCOI, and eIACUC applications.

ARC is available via Internet connection 24 hours a day, 7 days a week.

If you have any questions about the ARC system, the ARC HelpDesk is available during regular business hours at (813) 974-2880 and by email at [RSCH-arc@usf.edu](mailto:RSCH-arc@usf.edu).

## Accounts

In order to create and submit applications in ARC, you will first need to obtain an account by submitting a new user registration request.

### New Account Registration

To open your new ARC account:

1. Go to the ARC Web Site: <https://ARC.research.usf.edu/prod/>
2. Click **Register Here** on the right hand side of the page.

The screenshot shows the ARC web page with the following elements:

- Header:** USF UNIVERSITY OF SOUTH FLORIDA and arc logos, with a 'Login' link in the top right.
- Navigation:** A 'Home' button in a green box.
- Left Sidebar:** A list of links: Institutional Animal Care and Use Committee, Research Conflict of Interest, Institutional Review Board, What's New, Training Materials, Regulation and Guidance, and Contact Us.
- Main Content:**
  - Home:** A heading followed by a welcome message: "Welcome. The Division of Research Integrity & Compliance administers key research-related assurance and compliance programs required by federal and state agencies and programs for the conduct of research at USF. This site enables the division to manage all aspects of the Institutional Review Board process."
  - Full AAHRPP Accreditation!** A paragraph stating: "With this prestigious distinction, USF joins an elite group of top research universities and becomes the first AAHRPP accredited university in Florida which has its Human Research Protection Program accredited by AAHRPP."
- Right Side:**
  - Need an account?** A link to "Register Here" (highlighted by a red arrow).
  - Have an account?** Fields for "User Name:" and "Password:" with a "Log In" button.
  - Need Help?** Links for "Forgot Password" and "Forgot User Name".
- Footer:**
  - Division of Research Integrity & Compliance
  - ARC Help Desk (eIRB, eCOI, eIACUC): (813) 974-2880 - E-Mail: [rsch-arc@usf.edu](mailto:rsch-arc@usf.edu)
  - Mail: 12901 Bruce B. Downs Blvd, MDC35, Tampa, FL 33612-4799
  - Copyright © 2011, University of South Florida. All rights reserved

3. Complete the required fields ( \* ) and provide your USF Net ID, Employee ID, and USF or affiliate email address.
4. Select all relevant roles, such as Study Staff, PI, Department Approver, etc.
5. Click **Register**.
6. Within two business days your new account will be activated and you will receive an e-mail containing your account information (i.e., User Name & Temporary Password).

### Log In

1. Type your **User Name** in the login section on the right side of the ARC screen.
2. Type in your **Password**.
3. Click **Log In**.

The screenshot shows the ARC Home page. On the left is a navigation menu with links: Institutional Animal Care and Use Committee, Research Conflict of Interest, Institutional Review Board, What's New, Training Materials, Regulation and Guidance, and Contact Us. The main content area has a 'Home' heading and a welcome message. A 'Need an account?' section with a 'Register Here' link is at the top right. Below it, a 'Have an account?' section is highlighted with a red rounded rectangle. This section contains three numbered steps: 1. User Name: [input field], 2. Password: [input field], and 3. Log In [button]. Below the login form is a 'Need Help?' section with links for 'Forgot Password' and 'Forgot User Name'. The footer contains contact information for the Division of Research Integrity & Compliance and a copyright notice for 2011.

## Forgot Your User Name or Password?

If you ever forget your account credentials, you can have them emailed to you on the ARC Home page.

1. The **Forgot Password** and **Forgot User Name** options are available under **Need Help?**.

This screenshot is identical to the one above, showing the ARC Home page. However, the red rounded rectangle highlights the 'Need Help?' section at the bottom right of the login area. This section contains two links: 'Forgot Password' and 'Forgot User Name'. The rest of the page layout, including the navigation menu, main content, and footer, remains the same.

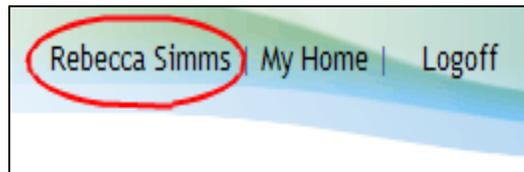
1. If you select **Forgot user name?**, you will be prompted to confirm your email address. Once confirmed, your user name will be emailed to you.

2. If you select **Forgot password?**, you will be prompted to confirm your user name and email address. Once confirmed, a new temporary password will be emailed to you. Upon log in, you will be required to change your password.

If you have forgotten both your user name and your password, select **Forgot user name?** first as it only requires your primary email address. After receiving your username, you can select **Forgot password?**.

## Account Changes

It is important to keep your account information current. To make changes to your account, click your name in the upper right hand corner of your screen to open your account properties.



Then make the necessary changes and click **Apply**. **Note** - For changes to your department affiliation and assigned roles, you will need to contact the helpdesk.

To change your password, click on your name (as described above). On your Account page, click the **Account** tab. Type in your old password, your new password, and your new password again in their respective boxes. Click **Apply**.

## Conflict of Interest Disclosure

If you or an immediate family member has a financial conflict of interest in research, you must disclose this information to the USF System Conflict of Interest Program. You can submit a disclosure upon submission of a grant application to one of the federal agencies or along with your applications to the Division of Research Integrity and Compliance if you are conducting research with human or animal subjects.

### Disclosing COI for Human Subjects Research

1. If you plan to submit your IRB application to the USF IRB, please complete the application in eIRB prior to submitting your COI Disclosure. This will allow you to choose the applicable study in which a conflict exists.
2. If you plan to submit your IRB application to Western IRB (WIRB), All Children's Hospital (ACH), the Florida Department of Health IRB, or other external IRB, you should submit the COI disclosure prior to submitting the application to the applicable IRB. This will ensure timely review and management of the conflict which must be in place prior to approval of the application.

## Creating a new eCOI Disclosure

To complete a COI disclosure, log into ARC at <https://arc.research.usf.edu/Prod>. You will be on your “Home Page.” From this page, you can submit IRB, IACUC or COI applications.

To submit a COI disclosure, select **New COI Disclosure** which can be found under the “Create” heading on the left hand side of the page.

Page for Rebecca Simms

**Study Staff**

**My Roles**  
Study Staff

**Quick Links**  
ARC Training Materials  
Division of Research Integrity & Compliance

**Human Subjects**  
New IRB Study  
Convert Paper Study

**Animal Subjects**  
New IACUC Study

**Conflict of Interest**  
New COI Disclosure  
New COI Interest Inventory

**Page for Rebecca Simms**

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to access an item.
- Monitor** - Check the progress of your submissions using the other tabs. Items under these tabs do not require any action by you.

**Inbox** IRB IACUC Approved Studies Profile COI

Displays all items which require action by the study team. Click on links for more information.

Filter by ID Go Clear Advanced

ID	Name	Date Modified	Type	Owner	State	Last State Change
RE4_Pro00000133	Reportable Event 4 for IRB Study #Pro00000133	8/17/2012 9:34 AM	Reportable Event	Max (IRB Staff), Orlando	Pre Submission	8/8/2012 4:14 PM
Pro00000095	Refugee Client Feedback	8/16/2012 4:00 PM	Study	Max (IRB Staff), Orlando	Changes Requested by Expedited Reviewer	8/16/2012 4:00 PM
Pro00000115	RCA guidance tool	8/10/2012 12:06 PM	Study		Pre Submission	3/2/2011 1:10 PM

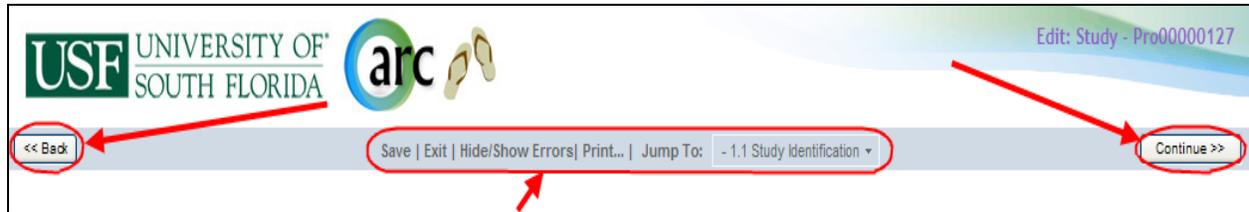
The application will open the disclosure **SmartForm** that gathers information on your research project.

## Working with Smart Forms

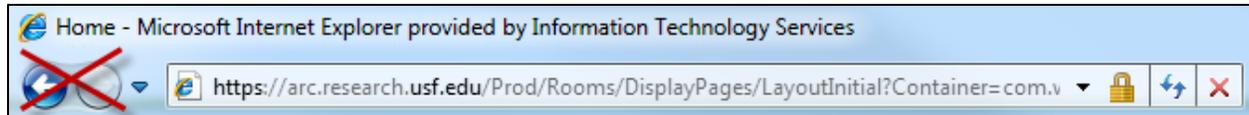
All applications in ARC use SmartForms which present only those questions that are relevant to your application. It is important that you respond to each question displayed on the SmartForms. Required fields are marked with a red asterisk \*.

You can answer text questions by typing directly into the text box or by pasting in text from other documents. **Add** function allows you to attach relevant documents or select your answer from a pre-populated list depending on the question.

Navigation controls are located in the navigation bar at the top and bottom of each page. Use the **Continue** and **Back** buttons to move to the next or last-viewed screen.



Use the SmartForm navigation controls instead of the controls in the browser bar (e.g., Internet Explorer, Firefox, Chrome, Safari, Opera).



Save your application by clicking **Save** or **Continue**.

**WARNING:** The **Back** button does not save changes. After you enter or edit data on a screen, click **Save** before going **Back**!

Use **Exit** to close the application and return to that application's Workspace.

**WARNING:** Always **Save** before exiting!

Each section and question is numbered for easy navigation and reference. Numbering is consistent through all SmartForm applications; however, remember that only the relevant questions for each specific application are displayed.

Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To** drop-down menu. The title of the displayed page will be **red**. Items not relevant to this application will appear gray in the Jump To menu.

**WARNING:** After you enter or edit data on a screen, click **Save** before using **Jump To**! The Jump To menu does not save.

## Filling out the eCOI Disclosure Form

Complete the application specific to the research project in which you have a conflict of interest.

1. Briefly describe in lay terms the purpose of the study in which you have a conflict:

<< Back Save | Exit | Hide/Show Errors| Print... | Jump To: - 1.4 Purpose of the Study, Role on the Study -> Continue >>

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**Purpose on the Study, Role on the Study** 1.4

1.4.1 \* Please explain the purpose of the study in lay terms, with adequate detail:

1.4.2 \* Please indicate your role(s) on the study. Select all that apply.

- Participated/participates in study design
- Conducts study initiation activities
- Assists with compliance with regulatory requirements
- Performs experimental portions of the study
- Records raw data from experimental portions of study
- Collects specimens
- Analyzes or interprets data
- Reports/presents study results
- Writes final report
- Presents study results
- Oversee all aspects of study
- Other (explain below)

**NOTE: The following roles are only applicable to studies involving human research**

- Screens/identifies potential subjects
- Obtains informed consent
- Educates participants, families, or staff
- Administers study medication (IV or PO)
- Enters data on Case Report Form (CRF)
- Conducts physical or neurological exams or clinical assessments
- Dispenses medication
- Reviews medical records or other clinical information

1.4.3 Please include any additional information regarding your role in the study that would assist the COI Committee in their deliberations:

2. There are different types of conflicts of interest; select the type(s) that best describe your situation.

<< Back Save | Exit | Hide/Show Errors| Print... | Jump To: - 2.1 Conflict Categories -> Continue >>

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**Conflict Categories** 2.1

Please indicate below the type of Reportable Financial Interests or Relationships held by you or your Immediate Family that may create a conflict or the appearance of a conflict with this USF System Research Project (select all that apply for either you or your Immediate Family).

2.1.1 Conflict Type: (Details of each conflict are available by selecting the items link)

- Ownership Interest in an Entity Related to the Research
- Consulting
- Speaker's Bureau or Similar Speaking Engagements
- Governing Position
- Advisory Boards
- Intellectual Property Interests
- Institutional Conflicts of Interest
- Employment of Immediate Family Member
- Other COIs

I affirm that I do not have any Reportable Financial Interests or Relationships that may be impacted by this USF System Research Project.

3. For each type of conflict, include detailed information regarding the conflict that will assist the USF System Conflict of Interest Committee in managing it. Detailed information is included by

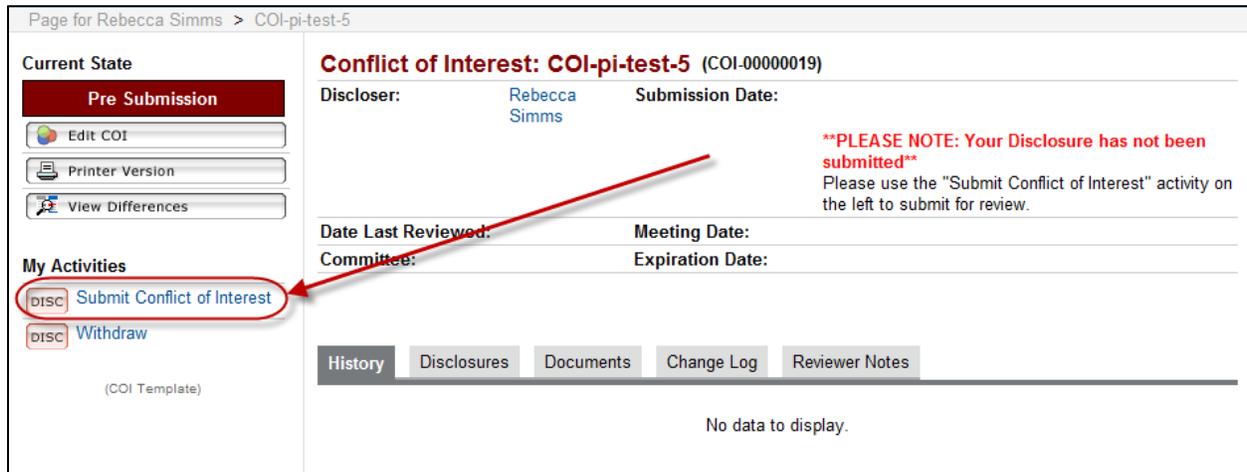
selecting “Add.” Selecting “Add” will provide you with a pop-up screen where the detailed information can be entered.

4. Identify the management controls currently in place to manage the conflict of interest you have in the research.
5. The last page is the Attestation page where you will select each of the boxes attesting to the information contained in the forms. Once you select each of the boxes, select “Finish” which will take you back to the home page of the disclosure. **Please note that the disclosure has not yet been submitted!**

## Submitting the Disclosure

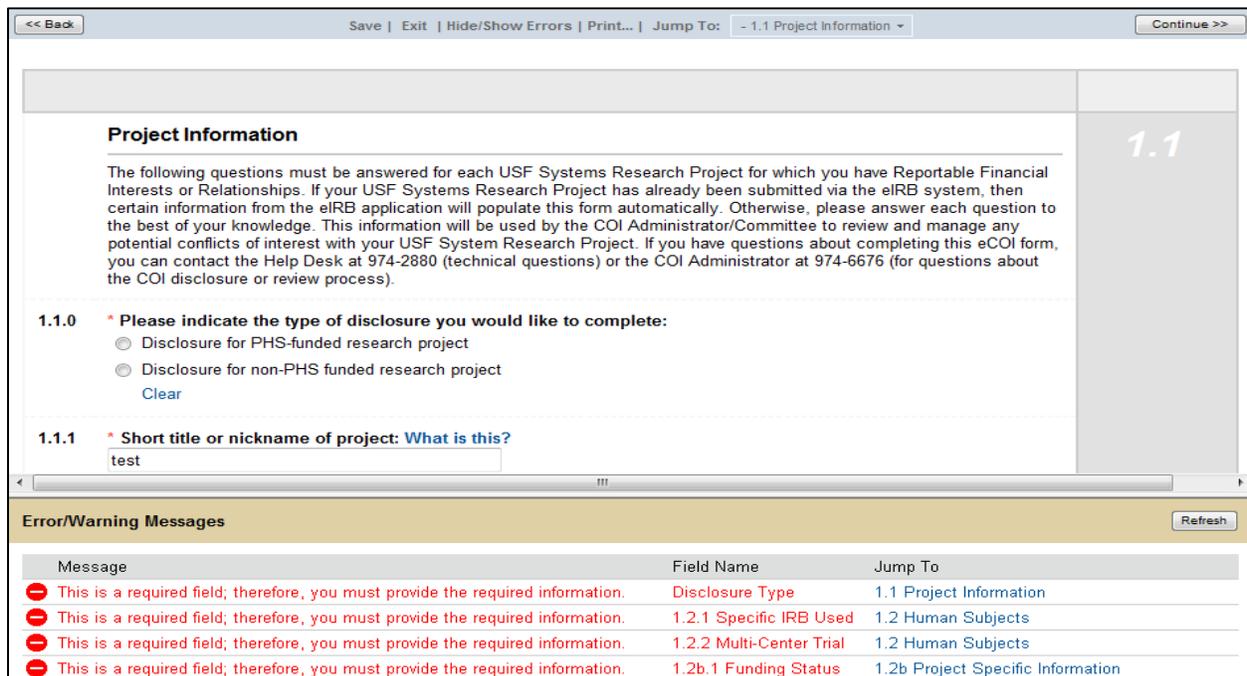
After completing the disclosure forms and answering all of the questions that are required, click “Finish” which will take you back to the home page of the disclosure. Then, select **“Submit Conflict of Interest”**

by clicking the button under “My Activities.” You can also withdraw the disclosure, should you choose to not take part in the research or if your conflict is eliminated.



When you select “**Submit Conflict of Interest,**” the system will identify any required questions that were not answered.

1. At any time while completing the disclosure forms, you can check for errors by clicking Hide/Show Errors at the top of the screen.
  - You can turn off this function by clicking **Hide/Show Errors** again.
  - Below is an example of a study with errors. If you click on the link under the *Jump To* column, it will take you directly to the page with the errors indicated.
  - When fixing errors, make sure to click the **Continue** button to save the changes and complete any new pages that may need to be filled out.



2. Submitting the conflict of interest disclosure form will route the application first to your supervisor and then to the USF System Conflict of Interest Administrator.
3. Your supervisor will acknowledge the disclosure or send questions back to you for review and comment.
4. To ensure the disclosure has been submitted, check the “Current State” of the application. In the top left hand corner of the home page, if the current state is “Pre Submission,” then the disclosure has not been submitted.
5. You can also assess whether or not a disclosure has been submitted by reviewing the History log. If submitted, you will see a new activity listed that shows COI Disclosure submitted.

Folder for Rebecca PI > COI-pi-2010-6

**Current State**

**Supervisor Review**

View COI  
Printer Version  
View Differences

**My Activities**

Add Supporting Documentation  
Email COI Administrator  
Withdraw

(COI Template)

**Conflict of Interest: COI-pi-2010-6 (COI-00000042)**

Discloser: Rebecca Simms (PI)      Submission Date: 12/15/2010

Date Last Reviewed:      Meeting Date:

Committee:      Expiration Date:

History   Disclosures   Documents   Change Log   Reviewer Notes

Activity	Author	Activity Date
Submitted Conflict of Interest	Simms (PI), Rebecca M	12/15/2010 11:10 AM EST

6. Your submission will continue through the eCOI review process.

## Additional Information

- Your Supervisor may have questions or concerns about the disclosure and will send them to you via the eCOI system. You must answer these questions within the system and send the disclosure back to your supervisor for additional review.
- You can withdraw your disclosure until it is in the hands of the USF System COI Program. Once the COI program receives the disclosure, you will not be able to withdraw or change the information unless requested by the COI Administrator.
- For more detailed information on accounts, how to navigate through eCOI, or how to create and submit a new disclosure, please feel free to contact the ARC Help Desk.
- The ARC Help Desk is available during regular business hours at (813) 974-2880 or [RSCH-ecoi@usf.edu](mailto:RSCH-ecoi@usf.edu).