

How to View and Attest to Documents in the UNC SOM Profile & Training System (PaTS)

1. After completing your profile in PaTS, you will receive automatic emails when a new task is assigned that is related to one of your selected responsibilities. The image below is an example of a notification from PaTS of a new assignment to review and attest to an SOP.

Email Notification from PaTS will appear as follows:

You have a new assigned task [PaTS]



New Notification from SOM PaTS

You have been assigned a new task in the SOM Profile and Training System (PaTS). Please click the link below or copy the url into your browser to view and complete your new task.

SOM SOP 401.1, Obtaining and Documenting Informed Consent from Adult Research Participants Attestation

Task Due Date: 6 Jan 2024

<https://pats.crso.unc.edu/app/tasks?id=2>

This is an automated message sent by SOM PaTS

2. To complete the new task, click on the link provided in the automated email. The UNC Single Sign-On will appear, log in using your UNC credentials/onyen. You may also login to PaTS directly and access the new task from your task list.

A screenshot of the UNC Single Sign-On login page. At the top left is the UNC logo (a building icon) and the text 'THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL'. Below this, the title 'Single Sign-On' is displayed in a large blue font. Underneath the title, the text 'Onyen -or- UNC Guest ID' is shown above a white input field. At the bottom of the form is a blue button with the word 'Next' in white text.

3. Upon logging in you will be taken to the PaTS home page. Click the My Task header on the navigation bar on the left-hand side to access active and completed tasks. Any newly assigned tasks will be in the My Active Tasks folder.

The screenshot shows the PaTS (UNC SOM Profile & Training System) home page. On the left is a dark blue navigation bar with links: Overview, My Profile, My Tasks (highlighted), PaTS Admin Console, CRAU Management, Training Catalog, Document Repository, and CRSO Tools. The main content area has a top bar with 'Notifications' and 'Logout' buttons. A yellow 'Under Development' warning box is present. Below is a breadcrumb 'PaTS >> My Tasks' and two buttons: 'My Active Tasks' (active) and 'My Completed Tasks'. The 'Current Tasks' section features a table with columns: Title, Type, Due Date, and Actions. A single task is listed: 'SOM SOP 401.1, Obtaining and Documenting Informed Consent from Adult Research Participants Attestation' with a due date of '6 Jan 2024'. The 'Actions' column contains a document icon and a trash icon. The table has a legend for 'Assigned to You' (yellow) and 'Completed by You' (green). Pagination shows 'Rows per page: 20' and '1-1 of 1'.

4. To review the SOP, select the highlighted page icon under Actions. This will open the Review Documents window.





This is a close-up of the 'Current Tasks' table. The table has a blue header with 'Current Tasks'. Below the header is a legend for 'Assigned to You' (yellow) and 'Completed by You' (green). The table has columns: Title, Type, Due Date, and Actions. The first row contains the task: 'SOM SOP 401.1, Obtaining and Documenting Informed Consent from Adult Research Participants Attestation' with a due date of '6 Jan 2024'. The 'Actions' column shows a document icon with a green highlight and a trash icon. The table has a legend for 'Assigned to You' (yellow) and 'Completed by You' (green). The table has a legend for 'Assigned to You' (yellow) and 'Completed by You' (green).


5. The left-hand side of the Review Document window displays the assigned SOP. Use the Next and Previous buttons at the bottom of the window to navigate between pages of the SOP.

The icons at the top of the screen allow for zooming, navigating out to the CRSO website, and downloading the document as a pdf. Open a pdf version of the SOP in your browser for full functionality of the cross references and hyperlinks embedded in the document.

The right-hand side of the Review Document window provides Document Information, an Attestation Statement and confirmation button, as well as an 'Ask a Question' link. Questions submitted through PaTS via this link will go directly to the PaTS team.

Review Document





SCHOOL OF MEDICINE

Standard Operating Procedure

SOP 401, Version 1	Issued by: SOM CRSO	Issue Date: 05.16.2022	Effective Date: 06.15.2022
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401.1: Obtaining and Documenting Informed Consent from Adult Research Participants

PURPOSE
This SOP describes the process for obtaining and documenting written informed consent from adult research participants or participants' legally authorized representatives.

SCOPE
This procedure applies to all SOM investigators and designated study personnel responsible for obtaining written informed consent from adult research participants or participants' legally authorized representatives.

BACKGROUND
Legally effective [informed consent](#) must be obtained from research participants (or their [legally authorized representatives](#) (LARs)) prior to their participation in human subjects research unless the IRB has approved a waiver of informed consent as allowed by the federal regulations.^{1, 6, 10, 12, 15, 23} The investigator is responsible for ensuring that informed consent is obtained and documented but may delegate this responsibility to members of the study team who are listed as study personnel on the IRB application and appropriately qualified by education, training, and experience. It is essential for investigators to carefully establish consent procedures and implement any necessary safeguards needed to ensure the rights of research participants.

Informed consent is a process that begins with the recruitment and screening of a potential participant, includes the signing of the IRB-approved [informed consent form](#) (ICF), and continues throughout the participant's involvement in a research study and often even beyond study termination. The participant or LAR must be provided with relevant information and be given the opportunity to provide ongoing voluntary consent during the study. Additionally, any communications to study participants or discovery of new information that may affect participants' safety or affect former participants must be communicated to the participants as part of the ongoing informed consent discussion, as determined by the IRB.

Note: Throughout the remainder of this SOP, any informed consent procedures referencing participants apply equally to the participant or the participant's LAR.

PROCEDURE

- 1. Prepare for the informed consent discussion**
 - Print or otherwise prepare one or more copies of the currently IRB-approved version of the ICF(s).
 - Do not cross-out or write-in any information on the ICF.
 - If feasible, provide the ICF to the participant prior to the informed consent discussion to allow an opportunity for them to review the form in advance.

Document Information

Document Title: Obtaining and Documenting Informed Consent from Adult Research Participants

Version: 1.0

Reference ID: SOP-401.1

Type:sop

Attestation

I, Katie Marsh, have reviewed and understand the contents of the document titled Obtaining and Documenting Informed Consent from Adult Research Participants (SOP-401.1), version 1.0.

Today: 9 Nov 2023

I Have Reviewed This Document

Have questions about this document?

Ask a Question

Page 1 of 10

Previous

Next

Page 1 of 10

Previous

Next

3

6. After reviewing the document, locate the Attestation statement with your name, the title of the document being attested to, the document version number, and today's date.

Once you are ready, select the 'I Have Reviewed This Document' button.

Attestation


I, [REDACTED], have reviewed and understand the contents of the document titled Obtaining and Documenting Informed Consent from Adult Research Participants (SOP-401.1), version 1.0.

Today: 9 Nov 2023

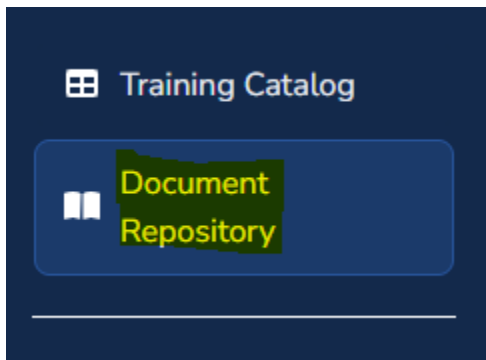
I Have Reviewed This Document

7. After selecting, 'I Have Reviewed This Document,' a confirmation will appear at the top of your window with today's date.


Review Document

 You attested to reviewing this document on 9 Nov 2023

8. If, at any point, you would like to navigate back to an SOP you have attested to select 'Document Repository' from the navigation bar on the left-hand side of your screen. A list of documents assigned to you will appear. A green vertical bar indicates the document titles that you have reviewed and attested to.




Document Repository			
Assigned to You Completed by You			
DENSITY COLUMNS FILTERS			
Document Title	Document Type	Category	Version
1 Obtaining and Documenting Informed Consent from Adult Research Participants	sop		1.0
1 Performing the Responsibilities of the Principal Investigator	sop		1.0
1 row selected			
Rows per page: 20 1-2 of 2			

9. To open a document from the Document Repository, click  icon. This will open a new window with a description of the document and a button labeled 'Go To Document'.

Document Repository

SOM SOP 401.1, Obtaining and Documenting Informed Consent from Adult Research Participants Attestation


 You completed this task on 2023-11-09T17:45:30.000Z

REFERENCE ID:

Description

This SOP describes the process for obtaining and documenting written informed consent from adult research participants or their legally authorized representative.

GO TO DOCUMENT



10. If you have attested to older versions of a document, the title will note Multiple Versions at the end. Once you select the document or SOP to view, all versions will be accessible for viewing, select 'Go To Document' to access the document.

SOM SOP 401, Obtaining and Documenting Informed Consent from Adult Research Participants Attestation (Multiple Versions)

✓ You last completed this task on 13 Nov 2023

REFERENCE ID:SOP-401

Description

This SOP describes the process for obtaining and documenting written informed consent from adult research participants or their legally authorized representative.

Assigned to You Completed by You

DENSITY COLUMNS FILTERS

Document Version	Completed Date	
1.0	25 Apr 2023	GO TO DOCUMENT
2.0	13 Nov 2023	GO TO DOCUMENT

11. After selecting 'Go To Document' the Review Document window will re-open. It will now show the document, along with the attestation confirmation at the top. If the attestation has already been completed, the right-hand side will no longer show the Attestation Statement. However, the Document Information and Ask a Question link will always be available.

Review Document

✓ You attested to reviewing this document on 9 Nov 2023

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UNC | **SCHOOL OF MEDICINE** | **Standard Operating Procedure**

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Page 1 of 10 Previous Next

Document Information

Document Title: Obtaining and Documenting Informed Consent from Adult Research Participants

Version: 1.0

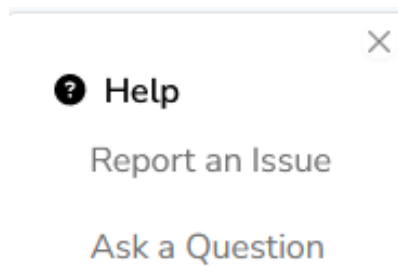
Reference ID: SOP-401.1

Type:sop

Have questions about this document?

🔔 Ask a Question

12. For questions or feedback related to PaTS, select the Help tab at the bottom right-hand side of your screen.



To learn more about creating and updating 'My Profile' in PaTS see
[Instructions for Creating and Updating My Profile in PaTS](#)
available on the CRSO website.