


Submit a Continuing Review or Final Report (formerly OHR-9)

1. From the iRIS homepage, navigate to Featured Study Operations.



My Workspaces

Study

Hello Tracy Marcelis
your last login was
08-24-2022 15:47
(You are working under someone else's account.)

Featured Study Operations

Create a New Study

Start a Submission Form for one of My Studies

View the Current Approvals for one of My Studies

View the Submission History for one of My Studies

View and Manage My Studies

Submissions in Process

3

All Tasks

Study Tasks

All Tasks


Outstanding

Completed

All Tasks

Study Tasks

2. Click on Start a Submission Form for one of My Studies



Workspaces

Study

Hello Tracy Marcelis
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Featured Study Operations

Create a New Study

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View the Current Approvals for one of My Studies

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View and Manage My Studies

All Tasks

Outstanding

Completed

3. Select the study you want to submit a Continuing Review or Final Report for.

All

Draft

4 result(s) found...

Select a Study

Study Status

Review Board

Approved

IRB

Draft

IRB

Submitted to IRB

IRB

Submitted to IRB

IRB

Click to open the study

4. Click on Continuing Review or Final Report (formerly OHR-9)

Draft

Study Status

Review Board

Approved

Draft

Submitted to IRB

Submitted to IRB

Submission Forms

	Version List	Start a new Submission	Edit Incomplete Submissions
Adding/Removing Study Personnel			
Amendment to Research Protocol			
Annual Check-in Form for Exempt and No Further Continuing Review Studies			
Continuing Review or Final Report (formerly OHR-9)			
External IRB - Annual Update and Closure			
IRB Reliance Agreement Follow-up Form			
Request for Acknowledgement/Receipt			

5. Click on Add a New Form

Review Studies

Principal Investigator

Add a new Form

6. Answer the questions in section 1.0. ...

Jefferson

My Workspaces

Account: Tracy Marcelis

Home! You have switched accounts. }

Department: TJU - - *Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information

Path: Home

IRB Number: IRISID-2022-0768

PI: Marcelis, Tracy

Study

Continuing Review or Final Report (formerly OHR-9) - (Version 1.0)

Calendar

Help

My Profile

Return to your account

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

1.0

Thomas Jefferson University Office of Human Research Continue ...

1.0

Thomas Jefferson University
Office of Human Research
Continuing Review or Final Report (formerly OHR-9)

1.1 Name of person completing this form:

Tracy Marcelis

1.2 Protocol Information:

IRB #:

IRISID-2022-0768

Study Title:

Tracy Marcelis - Training #3 8/8/22

TJU sponsored programs account number:

PI:

Tracy Marcelis

Department:

TJU - - *Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information

Funding Agency:

1.3 Financial Information:

ORA ACCOUNT NUMBER (if applicable):

DEPARTMENT CHARGE CODE:

1.4 Type of application:

☒ Continuing Review

☐ Final Report

7. In section 1.4, you will indicate if you are submitting a Continuing Review or Final Report.

DEPARTMENT CHARGE CODE:

1.4 Type of application:

☒ Continuing Review

☐ Final Report

1.5 Level of IRB Review

The level of IRB review (Full or Expedited) is noted on your ini selecting "Items" for the Approved Study.

Full

8. Click on Save and Continue to Next Section



Calendar



Help



My Profile ▾

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Refresh Constant Fields

Save Section

Save and Continue to Next Section

9. Attach the application.

Section view of the Form	Entire view of the Form
<div>1.0 Thomas Jefferson University Office of Human Research Continu ...</div> <div>2.0 Attaching a study application</div>	<div>2.0 Attaching a</div> <div>2.1 Read Carefully:</div> <p>The study application must be included with a continuing review application. Attach the study application here. If you have not already create continuing review application until the study application has been attached in this section.</p> <div> Click here to attach the application.</div> <p>No Application has been associated with this submission.</p>

10. Select the Master Application

Carefully:

application must be included with a continuing r
g review application until the study applica

Click here to attach the application.

tion has been associated with this submission.



Select the application that you would like to

Select	Show Rev.	Edit/ View	Form Name
<input checked="" type="radio"/>			Master Application (Version 1.0)

11. Click on Save Attachment

Print Friendly

Refresh Constant Fields

Save Se

ach and then click Save Attachment

Save Attachment

	Approved	Create a Revised Application
	Yes	<div><div></div><div>Add Revision</div></div>

atch it here. You cannot proceed with the

12. Click on Save and Continue to Next Section

Calendar

?

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My Profile

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Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

you can attach it here. You cannot proceed with the

13. Answer the FDA regulation question(s) in section 3.0.

Account: Tracy Marcellis Home(You have switched accounts.)
Department: TJU - - *Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information
Path: Home

Calendar Help My Profile Return to your account

Numbers: **IRISID-2022-0768** Study Continuing Review or Final Report (formerly OHR-9) - (Version 1.0) Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Entire view of the Form

3.0FDA Regulation

3.1 Is your study FDA Regulated?

☐ Yes ☐ No

Note: FDA-regulated studies involve investigational drugs, devices, or biologic products, or products approved by FDA that are used in a study in an off-label manner. These products may or may not be associated with an IND#, IDE#, or HDE#

14. Click on Save and Continue to Next Section

Calendar Help My Profile Return to your account

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Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

15. Answer the question in section 4.0 regarding the status of the study.

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Entire view of the Form

4.0Study Status

4.1 Has this study progressed to the point that it involves only one or both of the following?

Check all that apply:
☐ Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;
☐ Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
☐ N/A

4.2 Is this a multi-site study that is under single IRB oversight by Jefferson IRB?

☐ Yes ☐ No

4.3 Site-specific status:

Entry 1

Site Name:

Check as applicable:

☐ Study is active and subject recruitment/chart review/tissue collection is ongoing.
☐ Chart review/tissue collection is completed. Study is in data analysis.
☐ Enrollment is closed.

If enrollment is closed, check as applicable:
☐ Subjects are receiving study treatment or are undergoing study procedures. (A new stamped consent form will not be issued.)
☐ Study is in follow-up. Subjects are not receiving study treatment. (A new stamped consent form will not be issued.)
☐ A new stamped consent form is required.

Study has expired:
☐ Study has expired. PI certifies that no subjects were enrolled or study procedures occurred after the expiration date.

Study is suspended:

16. Click on Save and Continue to Next Section

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Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

17. Complete section 5.0 regarding enrollment and risk.

Account: Tracy Marcellis Home! You have switched accounts.)
Department: TJU - - *Your Department needs to be updated. Please submit a Servicehow ticket to provide this information
Path: Home

My Workspaces IRB Number: IRISID-2022-0768 Study Continuing Review or Final Report (formerly OHR-9) - (Version 1.0)

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

Thomas Jefferson University Office of Human Research Continues ...
1.0 University Office of Human Research Continues ...
2.0 Attaching a study application
3.0 FDA Regulation
4.0 Study Status
5.0 Enrollment & Risk Data

5.0 Enrollment & Risk Data

5.1 Please complete the following information for Jefferson and each external site under Jefferson IRB oversight:

Date of first IRB approval:
Date of most recent continuing review approval:
Period of that approval (see approval letter):
If this is first continuing review, then provide period of first IRB approval.
☐ 1 yr
☐ 6 mo
☐ Other

Entry 1
Click here to add another entry

Entry Name:
Date of first on-site subject enrollment:
Date of most recent on-site subject enrollment:

5.2 Does the study involve interaction with subjects?
☐ Yes ☐ No

5.3 Is the study a registry?
☐ Yes ☐ No

5.4 Is the study a collection of pre-existing (stored) biological specimens collected for reasons other than this study?
☐ Yes ☐ No

18. Click on Save and Continue to Next Section

21. Complete the Progress Report in section 7.0.

Jefferson
UNIVERSITY

Account: Tracy Marcellis Home (You switched accounts.)

Department: T3J - - *Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information

Path: Home

Calendar

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My Workspaces

IRB Numbers: **IRISID-2022-0768**

PI: Marcellis, Tracy

Study

Continuing Review or Final Report (formerly OHR-9) - (Version 1.0)

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

Entire view of the Form

1.0 Thomas Jefferson University Office of Human Research Continue ...

3.0 Attaching a study application

3.0 FDA Regulation

4.0 Study Status

5.0 Enrollment & Risk Data

6.0 Demographic Table

7.0 **Progress Report**

7.0 Progress Report

7.1 Interim findings: Provide at least a 3-4 sentence synopsis describing what has or has not occurred in the study, plus data related to subject responses to intervention, if applicable:

Hint: Attach copies of any publications or abstracts that have resulted from the research. If Jefferson is the IRB of Record for a multi-site study ensure that interim findings encompass all sites.

Font Family 12

Rich Text Editor

7.2 Has there been any subject withdrawals, lost to follow-ups, and/or deaths since initial approval or most recent continuing review approval?

☐ Yes ☐ No

7.3 Describe any subject grievances or complaints:

Font Family 12

Rich Text Editor

22. Click on Save and Continue to Next Section

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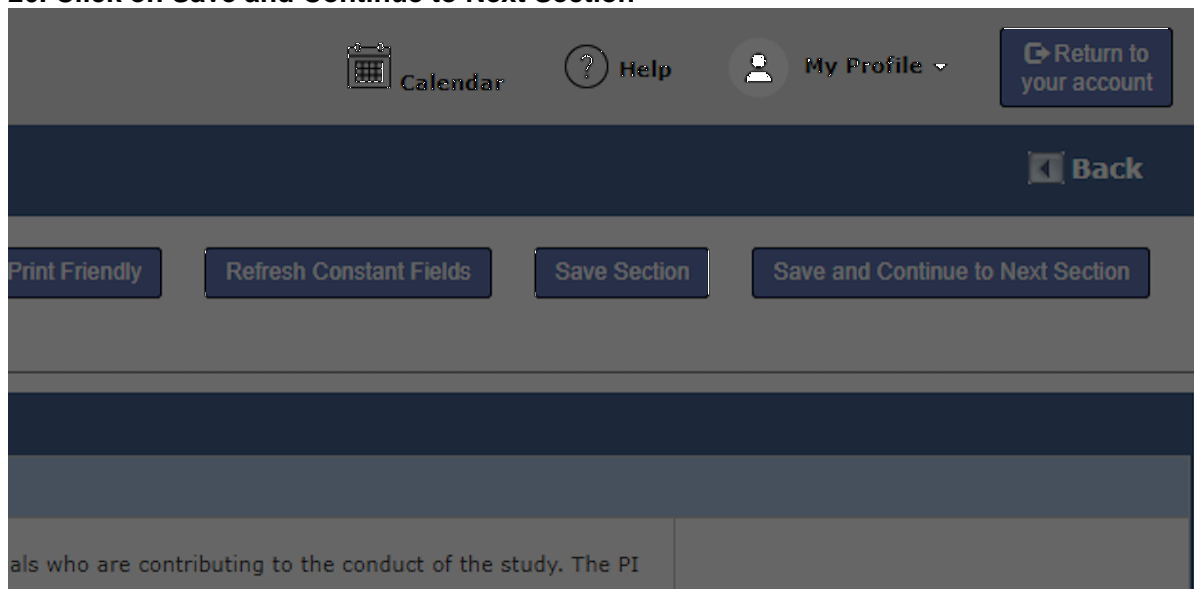
[Print Friendly](#)
[Refresh Constant Fields](#)
[Save Section](#)
[Save and Continue to Next Section](#)

, if applicable:

sites.

23. Attach all required documents in section 8.0.

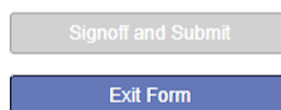
26. Click on Save and Continue to Next Section



The screenshot shows a web form interface with a dark grey header and a dark blue navigation bar. The header contains icons and links for 'Calendar', 'Help', 'My Profile', and 'Return to your account'. The navigation bar has a 'Back' button. Below the navigation bar, there are four buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. The main content area is partially visible, showing a dark blue bar and a grey bar. The text 'als who are contributing to the conduct of the study. The PI' is visible at the bottom of the main content area.

27. Click on Signoff and Submit

are ready to send for signoff, click Signoff and Submit. Clicking Exit Form will send this back t



The screenshot shows two buttons stacked vertically. The top button is light grey and labeled 'Signoff and Submit'. The bottom button is dark blue and labeled 'Exit Form'.

28. You will be redirected to the signoff. Click Ok.

Form has been Completed!

Your application is complete and you are ready to send for signoff, click Signoff and Submit. Clicking Exit Form will send this back to your stu

You are required to signoff on the submission.

You will now be redirected to the signoff screen to apply your electronic signature.

You can monitor the submission progress with the Submission Status - In Progress.

OK

29. Complete the signoff.

Jefferson

ACCOUNT: tracy.marcelis - Home. You have switched accounts. J

Department: T3U - - Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information

Path: home

My Workspaces

Study

Submission Routing Signoff

Back

Save Signoff

Calendar

Help

My Profile

Return to your account

Study Title: Tracy Marcelis - Training #3 8/8/22

Submission Reference Number: 001855

Create PDF Packet

Include in PDF Packet	Compare to Last Approval	View in Separate Window	Submission Component Name - Version
Submission Form(s)			
<input type="checkbox"/>	<input type="checkbox"/>		Continuing Review or Final Report (formerly OHR-9) - (Version 1.0)
Application			
<input type="checkbox"/>	<input type="checkbox"/>		Master Application - (Version 1.0)

PI Certification:

I certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that:

Check where relevant:

☐ Under federal mandate, there is a signed consent form on file with the Principal Investigator for every subject studied at Jefferson, and each subject at Jefferson has received a signed copy of the consent form.

If this is not true, please provide a brief explanation:

Do not check if no subjects enrolled.

-OR-

☐ The Institutional Review Board approved the study without a need to obtain written consent from subjects.

Tracy Marcelis, as Principal Investigator

Do you Approve or Deny this submission?

☐ Approve ☐ Deny

Comments:

Click here to add comments.

Save Signoff



30. Click on Approve or Deny.

...true, please provide a brief explanation:
if no subjects enrolled.

-OR-

...tutional Review Board approved the study without a need to obtain written consent from subjects.

Tracy Marcelis, as Principal Investigator

Do you Approve or Deny this submission?

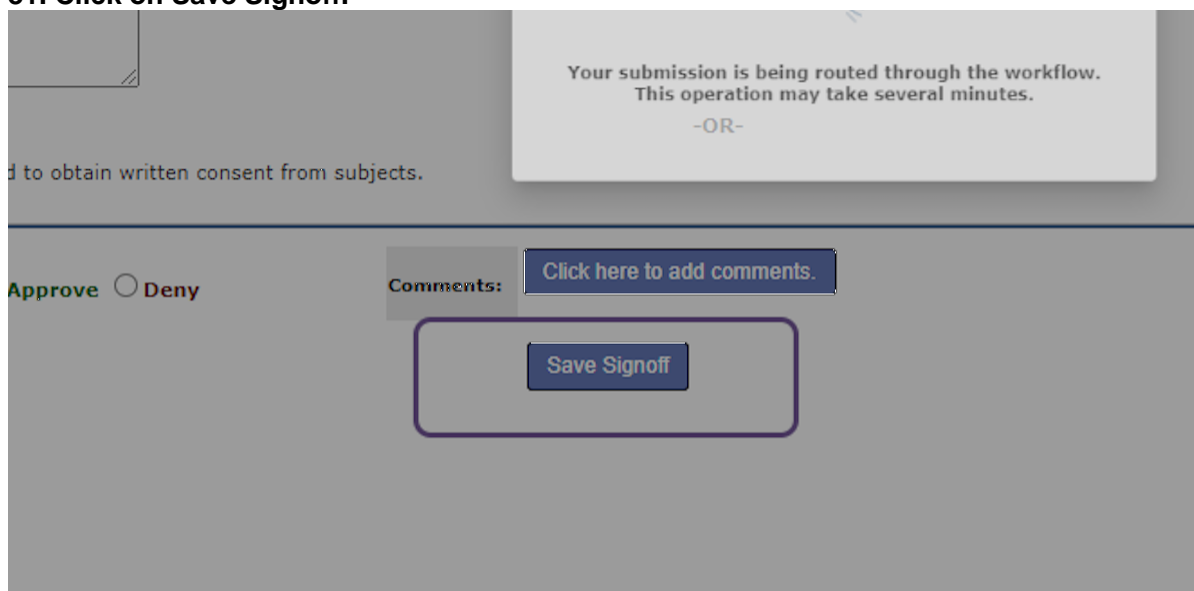
☒ Approve ☐ Deny

Comments:

Click here to add comments.

Save Signoff

31. Click on Save Signoff.



The screenshot shows a web interface for a workflow sign-off. At the top, a light gray box contains the text: "Your submission is being routed through the workflow. This operation may take several minutes." Below this, the text "-OR-" is centered. On the left, there is a section with the text "d to obtain written consent from subjects." and a "Comments:" label. To the right of "Comments:" is a button that says "Click here to add comments." Below the "Comments:" label is a rounded rectangular box containing a "Save Signoff" button. To the left of the "Save Signoff" button, there are radio buttons for "Approve" and "Deny".

Your submission is being routed through the workflow.
This operation may take several minutes.

-OR-

d to obtain written consent from subjects.

Approve ☐ Deny

Comments: Click here to add comments.

Save Signoff

This workflow was created with Tango.