

Kindly note:

- Internet Explorer is not compatible with MEOS; some functionality may be lost.
- It is suggested that Chrome, Edge, Safari or Opera, amongst others be used.

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MEOS
(MANDELA ETHICS ONLINE SYSTEM)

AMENDMENTS/EXTENSIONS/CLOSURES
(Research Ethics Committee – Human)

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1. Amendments

- Amendments can only be requested for a protocol that has been granted approval.
- Amendments must be requested and approved PRIOR to the implementation of the amendment.
- Retrospective approval cannot be granted for an amendment.
- Failure to request an amendment prior to its implementation may lead to the suspension of the study.

1.1. Applying for an Amendment

Log in to your MEOS work area (meos-apply.mandela.ac.za) and click on the project for which you require an amendment.

Projects				
Search Projects				
Project Title	Project ID	Owner	Date Created	Date Modified
> MEOS Training	1160	Ms Michelle Barnett	18/06/2024 08:14	25/06/2024 07:44

Check that the status is “Approved”, then click [Create Sub Form].

Action Required on Form	Status	Review Reference	Date Modified
No	Approved	2024-LAW-1160-1465	25/06/2024 07:44

Select the Amendment form and click the green [Create] button.

Action Required on Form
No

Create Subform

Select the sub-form that you would like to apply to this form

- ✓ Please Select...
- REC-H: Adverse Event
- REC-H: Amendment**
- REC-H: Documentation Upload
- REC-H: Progress-Extension/Closure Report
- REC-H: Violations/Deviations Report

Complete the form. Share it with your supervisor if your supervisor does not already have access to your entire project. Do not forget to sign it and request the signature of the PRP (if applicable). After all required signatures are on the form, the application will automatically submit for review.

2. Annual Progress Reports (APR)

- An Annual Progress Report (APR) must be submitted on an annual basis.
- Reminder emails are sent approximately 50-days and 30-days before ethics approval for a study lapses.
- An Annual Progress Report is submitted for one of the following reasons:
 - To request an extension of data collection
 - To register the data collection/study as complete
 - To notify REC-H of the discontinuation of the study
- Failure to submit an APR may lead to suspension of the study.

2.1. Creating an Annual Progress Report

Log in to your MEOS work area (meos-apply.mandela.ac.za) and click on the project for which you are creating an annual progress report.

Projects					
Search Projects					
Project Title	Project ID	Owner	Date Created	Date Modified	
> MEOS Training	1160	Ms Michelle Barnett	18/06/2024 08:14	25/06/2024 07:44	

Click [Create Sub Form].

Project Tree		
<div style="display: flex; justify-content: space-between;"> <div> <ul style="list-style-type: none"> Project Roles </div> <div> <ul style="list-style-type: none"> Create Sub Form View as PDF </div> <div> <ul style="list-style-type: none"> Share </div> </div>		
<ul style="list-style-type: none"> MEOS Training <ul style="list-style-type: none"> REC-H: Initial Application (Human) 		
Action Required on Form	Status	Review Reference
No	Approved	2024-LAW-1160-1465

Select the Progress-Extension/Closure Report and click the green [Create] button.

Project Tree		
<div style="display: flex; justify-content: space-between;"> <div> <ul style="list-style-type: none"> Project Roles </div> <div> <ul style="list-style-type: none"> Create Sub Form View as PDF </div> <div> <ul style="list-style-type: none"> Share </div> </div>		
<ul style="list-style-type: none"> MEOS Training <ul style="list-style-type: none"> REC-H: Initial Application (Human) 		
Action Required on Form	Status	Review Reference
No		

Create Subform ✕

Select the sub-form that you would like to apply to this form

- ✓ Please Select...
- REC-H: Adverse Event
- REC-H: Amendment
- REC-H: Documentation Upload
- REC-H: Progress-Extension/Closure Report
- REC-H: Violations/Deviations Report

Create
Close

2.2. Applying for an Extension

Kindly note:

- Applications for extension must be submitted 4-6 weeks before approval lapses.
- An extension cannot be granted for a study if the ethics approval has lapsed.
- If ethics approval has lapsed, a new application for review and approval must be submitted through MEOS.
- Data collection cannot continue if ethics approval has lapsed.

After creating the Progress-Extension/Closure Report, click on the first question – Protocol Information.

Section	Questions
Section 1: Protocol Information	<input type="button" value="Protocol Information"/> <input type="button" value="Researchers"/>
Section 2: Continuing Study	<input type="button" value="Continuing Study"/>
Section 3: Study Closure	<input type="button" value="Study Closure"/>
Section 4: Study Discontinuation	<input type="button" value="Study Discontinuation"/>
Section 5: Divergence from Approved Study	<input type="button" value="Divergence from Approved Study"/>
Section 6: Monitoring and Audit Activities	<input type="button" value="Other Monitoring and Audit Activities"/>
Section 7: Declarations and Signatures	<input type="button" value="Declarations and Signatures"/>

In question 1.1, select “Extension of ethics approval”.

1.1 This progress report is for :
<input checked="" type="radio"/> Extension of ethics approval
<input type="radio"/> Closure of a study
<input type="radio"/> Discontinuation of a study

Complete the form. Share it with your supervisor if your supervisor does not already have access to your entire project. Do not forget to sign it and request the signature of the PRP (if applicable). After all required signatures are on the form, the application will automatically submit for review.

2.3. Submitting a Closure of Data Collection/Study Report

Kindly note:

- If no further data collection is envisaged or the study is complete, a progress report for the purpose of closure can be submitted.
- A closure report can be submitted at any time.

After creating the Progress-Extension/Closure Report, click on the first question – Protocol Information.

Section	Questions
Section 1: Protocol Information	Protocol Information Researchers
Section 2: Continuing Study	Continuing Study
Section 3: Study Closure	Study Closure
Section 4: Study Discontinuation	Study Discontinuation
Section 5: Divergence from Approved Study	Divergence from Approved Study
Section 6: Monitoring and Audit Activities	Other Monitoring and Audit Activities
Section 7: Declarations and Signatures	Declarations and Signatures

In question 1.1, select “Closure of a study”.

1.1 This progress report is for :
<input type="radio"/> Extension of ethics approval
<input checked="" type="radio"/> Closure of a study
<input type="radio"/> Discontinuation of a study

Complete the form. Share it with your supervisor if your supervisor does not already have access to your entire project. Do not forget to sign it and request the signature of the PRP (if applicable). After all required signatures are on the form, the application will automatically submit for review.

2.4. Submitting a Discontinuation of Study Report

Kindly note:

- For the discontinuation of a study and therefore the data collection for which ethics approval was granted, a discontinuation/closure report should be submitted no later than 1 month after reaching such a conclusion.

After creating the Progress-Extension/Closure Report, click on the first question – Protocol Information.

REC-H: Progress-Extension/Closure Report

Section	Questions
Section 1: Protocol Information	Protocol Information Researchers
Section 2: Continuing Study	Continuing Study
Section 3: Study Closure	Study Closure
Section 4: Study Discontinuation	Study Discontinuation
Section 5: Divergence from Approved Study	Divergence from Approved Study
Section 6: Monitoring and Audit Activities	Other Monitoring and Audit Activities
Section 7: Declarations and Signatures	Declarations and Signatures

In question 1.1, select “Discontinuation of a study”.

1.1 This progress report is for :

Extension of ethics approval

Closure of a study

Discontinuation of a study

Complete the form. Share it with your supervisor if your supervisor does not already have access to your entire project. Do not forget to sign it and request the signature of the PRP (if applicable). After all required signatures are on the form, the application will automatically submit for review.