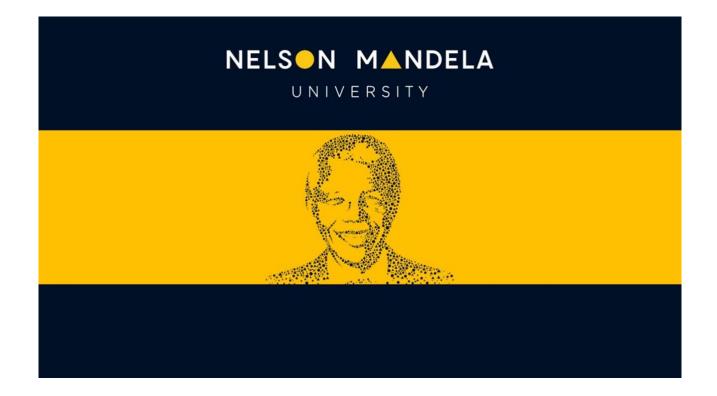
Kindly note:

- 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.



# MEOS (MANDELA ETHICS ONLINE SYSTEM)

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

Version 1.0 June 2024

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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 (<u>meos-apply.mandela.ac.za</u>) and click on the project for which you require an amendment.

Proje	ects				
Search I	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].

Project	Create Sub Form	Project Tree							
Roles	View as PDF	BEC-H: Initial Applic	ation (Human)						
		Action Required on Form		Sta	tus	Review Reference	e		Date Modified
		No		App	proved	2024-LAW-1160-1	1465		25/06/2024 07:44
		Navigation	Documents	Signatures	Collaborators	Submissions	Centre	History	

-	-		Project Tree			
Project	Create Sub Form	Share	MEOS Training	Create Subform	×	
Roles	View as PDF		Action Required on Form	Select the sub-form that you would like to apply to this form ✓ Please Select REC-H: Adverse Event		
			No	REC-H: Amendment REC-H: Documentation Upload REC-H: Progress-Extension/Closure Report REC-H: Violations/Deviations Report	Close	
			Navigation	ocuments Signatures Collaborators Submissions	Centr	re

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

### 2. Annual Progress Reports (APR)

- An Annual Progress Report (APR) <u>must be submitted on an annual basis</u>.
- 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 (<u>meos-apply.mandela.ac.za</u>) and click on the project for which you are creating an annual progress report.

Proje	ects				
Search F	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	Create Sub Form	Project Tree		
Roles	View as PDF	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.

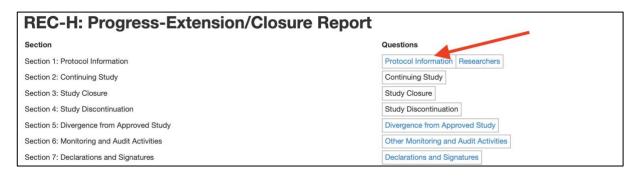
Project Create Sub Form S	Project Tree	Create Subform
Roles View as PDF		Select the sub-form that you would like to apply to this form ✓ Please Select  REC-H: Adverse Event
	Action Required on Form	REC-H: Average Event REC-H: Amendment REC-H: Documentation Upload Create Close
	No	REC-H: Violations/Deviations Report

#### 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.



In question 1.1, select "Extension of ethics approval".

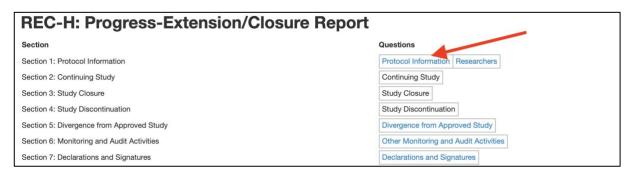


#### 2.3. Submitting a Closure of Data Collection/Study Report

#### 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.



#### In question 1.1, select "Closure of a study".



#### 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.

<b>REC-H: Progress-Extension/Closure Report</b>	
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".

