
RESEARCH INFORMATION MANAGEMENT SYSTEM (RIMS)

**Step-By-Step Guide to make your Protocol
Submissions for approval to conduct research in
Malawi.**

TABLE OF CONTENTS

CHAPTER 1	3
1.1 GENERAL INFORMATION	3
1.2 GETTING STARTED	3
CHAPTER 2	4
2.1 USING THE SYSTEM	4
2.2 REVISION	7
2.3 MAKING AMENDMENTS	8
2.4 MAKING A CLOSEOUT REPORT	11
2.5 SUBMITTING RENEWALS	12
2.6 SUBMITTING SAFETY AND NOTIFICATIONS	14
2.7 APPLYING FOR SAEs	16
2.8 SUBMITTING DEVIATIONS	17
CHAPTER 3	18
3.1 CONCLUSION	18

CHAPTER 1

1.1 GENERAL INFORMATION

This online platform supports the Research Ethics Committee (REC) to facilitate efficient research reviews and offers researchers an interface for data capture, management, validation, quality control, and regulatory compliance within research management processes.

1.2 GETTING STARTED

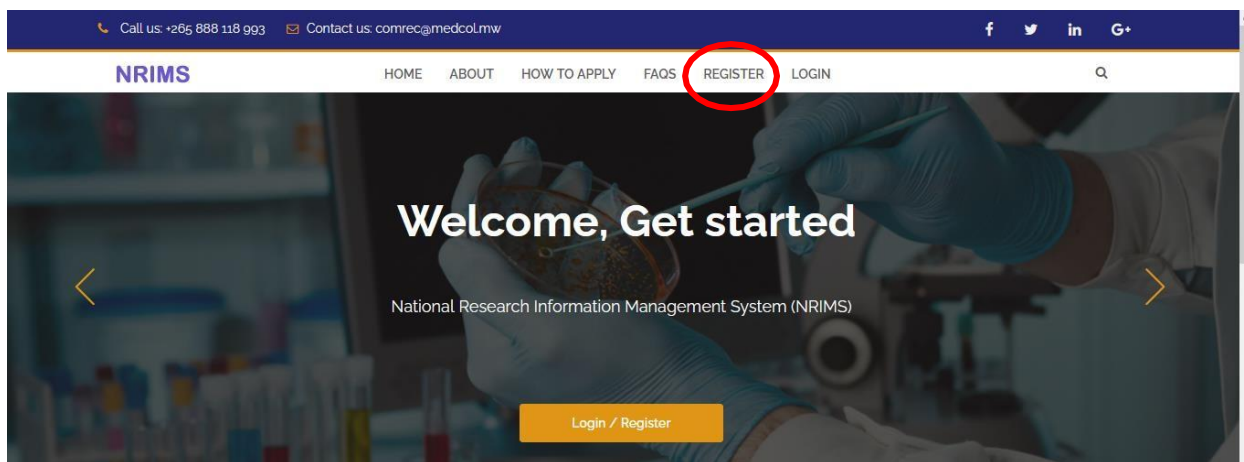
- To get started, access the RIMS website on <https://rims.kuhes.ac.mw/>
- To create an account and submit a protocol, follow the steps in SECTION 2, Section 2.1
- After Submitting your protocol, it will be reviewed, and feedback will be given through your registered email address.
- During the research process, expect to receive email notifications to stay updated. These emails will be sent at various stages, including account activation, protocol submission, completeness checks, and final protocol approval or rejection. These notifications are designed to ensure transparency and facilitate efficient communication between researchers and the REC.

CHAPTER 2

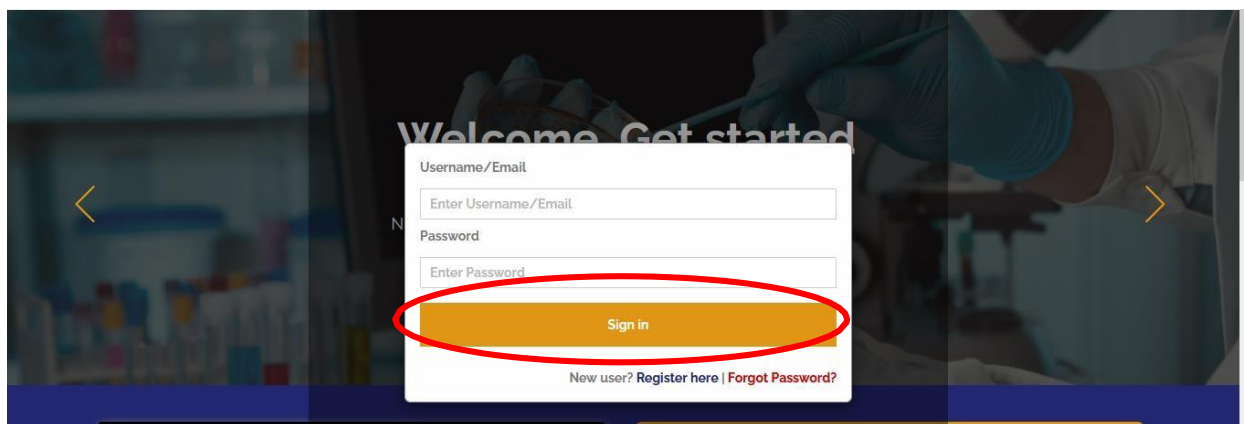
2.1 USING THE SYSTEM

Follow the steps below to create an account and submit a protocol to conduct research in Malawi. Take note of the red circles in each screenshot as they show important actions.

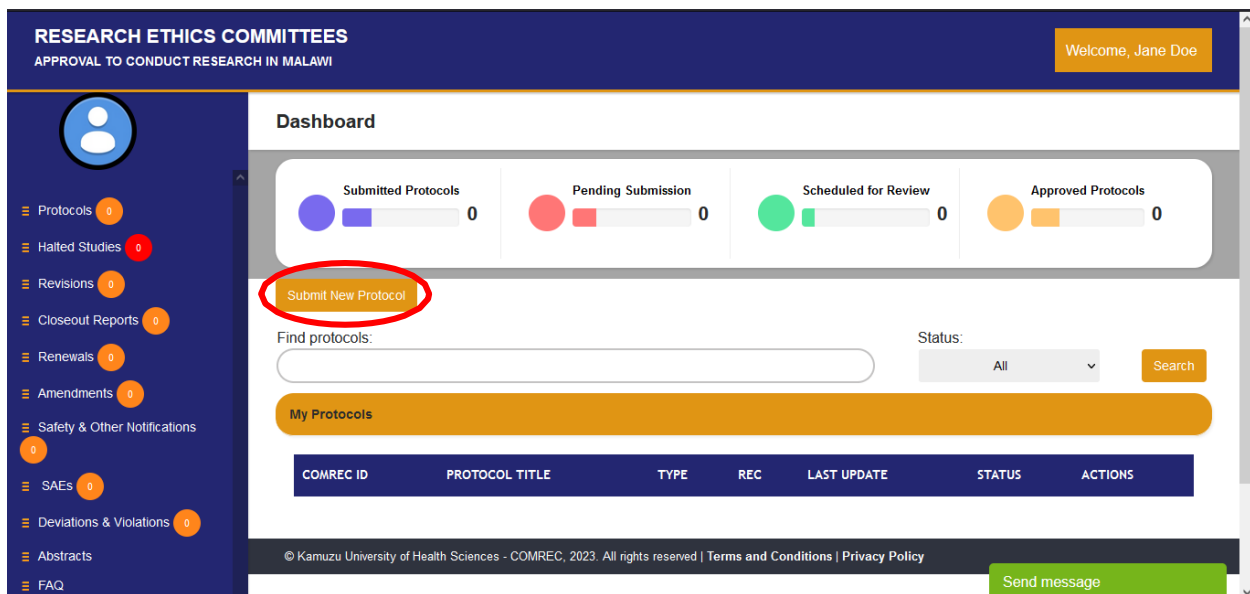
- 1. Click on “REGISTER” and fill in your information in all the required fields:**



- 2. After registration, you will receive an activation email (Check your Junk/Spam folder if it’s not in your inbox). Click on the activation link and you will be redirected to the home page, from here you can click on Login and fill in your username/email along with your password.**



3. You will be logged in and taken to the Research Ethics Committees (REC) workspace. Click on “Submit New Protocol” to begin submitting your protocol information. On the left side of the screen, you'll notice a side navigation bar with different options. This sidebar allows you to select the type of submission you wish to make to the REC. For instance, if you're submitting an amendment, navigate to the "Amendments" section and proceed from there. Each type of submission has its own dedicated section, so be sure to choose the appropriate section before proceeding with your submission.



4. Begin by filling in the project title and select the REC you are submitting to then click “Save and Next”:



- Protocols 0
- Halted Studies 0
- Revisions 0
- Closeout Reports 0
- Renewals 0
- Amendments 0
- Safety & Other Notifications 0
- SAEs 0
- Deviations & Violations 0
- Abstracts
- FAQ

Dashboard

- Protocol Information
- Protocol Details
- Study Description
- Study Population
- Budget
- Study Work Plan
- Attached Files
- Payments

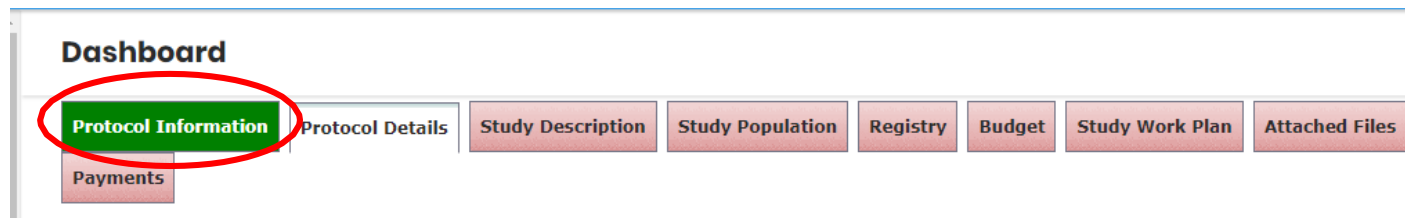
Project Title: *

REC: *

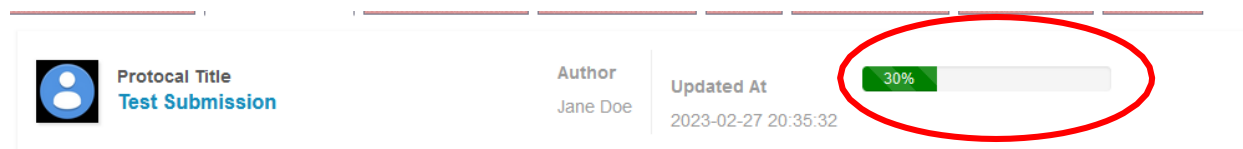
Save and Next

Send message

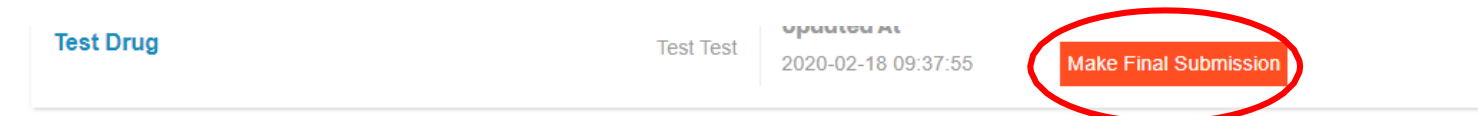
5. After filling in the required fields, the Protocol Information tab turns green, indicating completion of that section of your submission. If you proceed and a tab remains pink, this means that you have left out a certain section that needs to be filled on that tab.



6. The percentage in Green, shows your overall progress, as you proceed with different sections of the submission, the bar will fill gradually up until it reaches 100% at which point you can make your submission to the REC.



7. After all the Information has been filled with all the necessary documents attached, your overall progress will be at 100%, and the “Make Final Submission” button will pop up under your overall progress. Click on it to make your submission. Please note that you will not be able to make any edits after this point. If you need to make changes, please inform the REC members to reverse your submission, allowing you to edit.



8. After making your final submission, you will be able to view or print your submission, or view the comments made by the Reviewer.

Search interface with a search bar, a status dropdown menu set to "All", and a "Search" button.

Protocol Title	Type	REC	Last Update	Status	Actions
Test Drug Test Test - Test Inc,	Clinical Trial	Test UNCST Research Ethics Committee	2020-02-18 10:01:48	Waiting for Committee	+ View Submission + View Comments + Print Submission


2.2 REVISION/UPDATING A SUBMISSION

This section indicates how to provide revisions to a protocol that been deemed by the REC Admin to be incomplete or does not meet minimum requirements. of a submission.

9. If your protocol is rejected, in need of responses, or receives conditional approval by the REC, a button labeled 'Update Submission' will appear. You do not need to create a new protocol submission. Simply click on the 'Update Submission' button to work on the existing protocol that needs to be addressed. Remember to make sure to click the 'Save' button after updating every section you are updating. After making the necessary updates, resubmit your protocol for review.

Protocol Title	Type	REC	Last Update	Status	Actions
NXT Tool Deng Luka -	Engineering and Technology	Test UNCST Research Ethics Committee	2020-02-17 16:27:07	completeness check	+ View Submission + Update Submission + Print Submission

10. Update the necessary sections and click “Resubmit” when done.

 Protocol Title
NXT Tool

Author
Deng Luka

Updated At

100%

Resubmit

11. After resubmission, you will be redirected back to the REC workspace, and you can view or print your protocol as it gets reviewed

Protocol Title	Type	REC	Last Update	Status	Actions
NXT Tool Deng Luka -	Engineering and Technology	Test UNCST Research Ethics Committee	2020-02-20 15:54:59	Waiting for Committee	+ View Submission + View Comments + Print Submission

12. If your protocol gets approved, protocol status changes and a signed REC Approval Letter will be available for download.

2.3 MAKING AMENDMENTS

13. You'll be able to "Apply for Amendments" as well, if necessary. To do so navigate to the amendments button on the left then select apply for amendments button in red.

The screenshot displays the 'RESEARCH ETHICS COMMITTEES' dashboard for 'APPROVAL TO CONDUCT RESEARCH IN MALAWI'. The user is logged in as 'Jane Doe'. The dashboard includes a search bar for 'Find Ammendmnets' and a 'Status' dropdown menu. A table with columns for 'Project Title' and 'Status' is visible. The left sidebar contains navigation options: Protocols, Halted Studies, Revisions, Closeout Reports, Renewals, Amendments, Safety & Other Notifications, SAEs, Deviations & Violations, Abstracts, and FAQ. The 'Amendments' option is circled in red. A red button labeled 'Apply for Amendments' is also circled in red. A 'Send message' button is located at the bottom right.

14. After clicking on “Apply for Amendments”, you will be redirected to fill in the changes to be made and attach the necessary documents highlighted in red.

Click to add New Attachment

Protocol	Type	Language	Version	Date
----------	------	----------	---------	------

Please attach:

Proposal with Tracked Changes
Clean Copy
Cover letter
Proof of Payment

Changes to Consent Form: Are changes required?:

- No
- Yes

Changes to data collection tool: Are changes required?:

- No
- Yes

Changes to protocol: Are changes required?:

- No
- Yes

Are there changes to study districts? Please highlight districts :

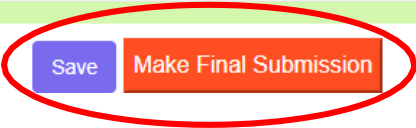
Online

15. Fill in all the information and click on the “Save” button to save your inputs, or “Make Final Submission” button to submit your amendments.

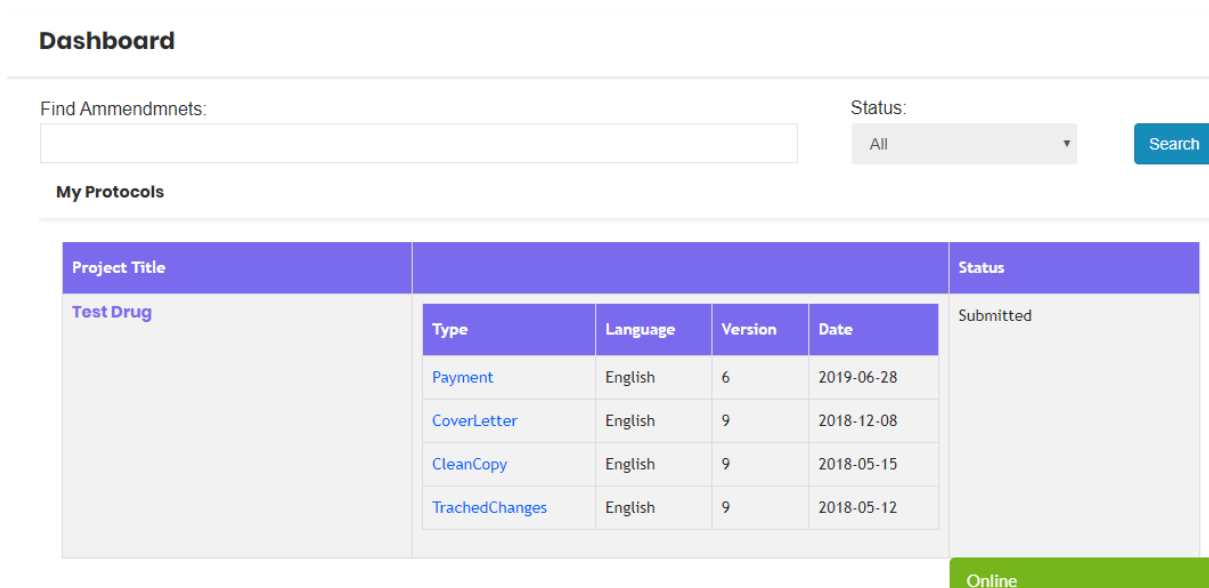
Are they changes to study districts? Please highlight districts :

Description of proposed changes:

Reason for Amendment/Modification:

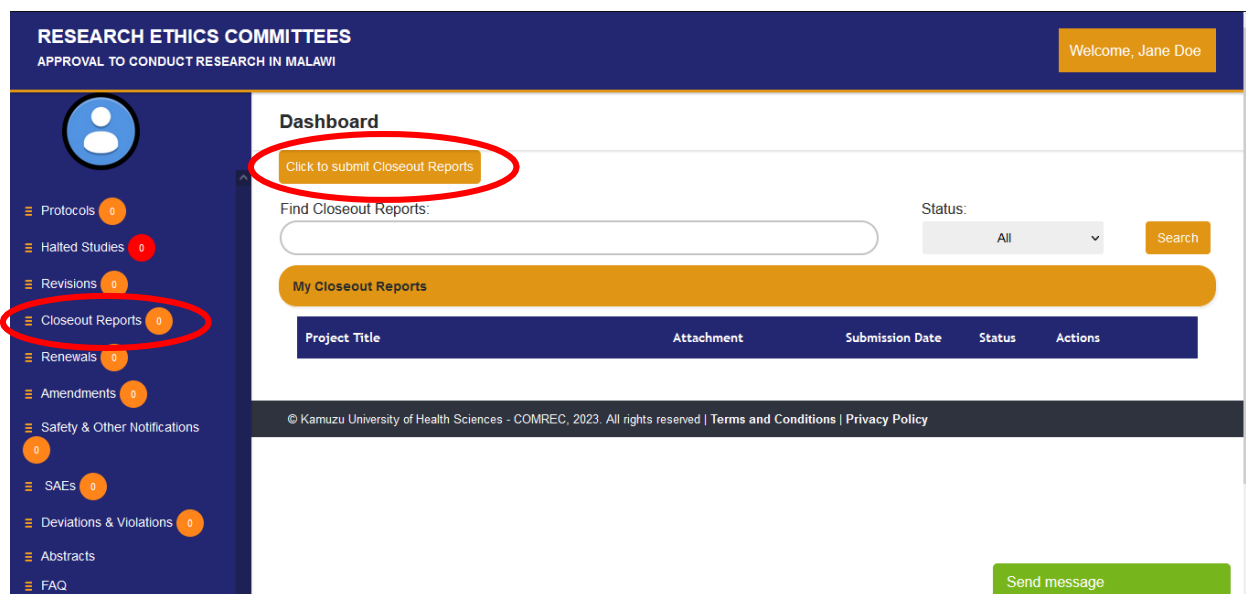


16. After submission, you will be redirected to the “Amendments” Section.



2.4 MAKING A CLOSEOUT REPORT

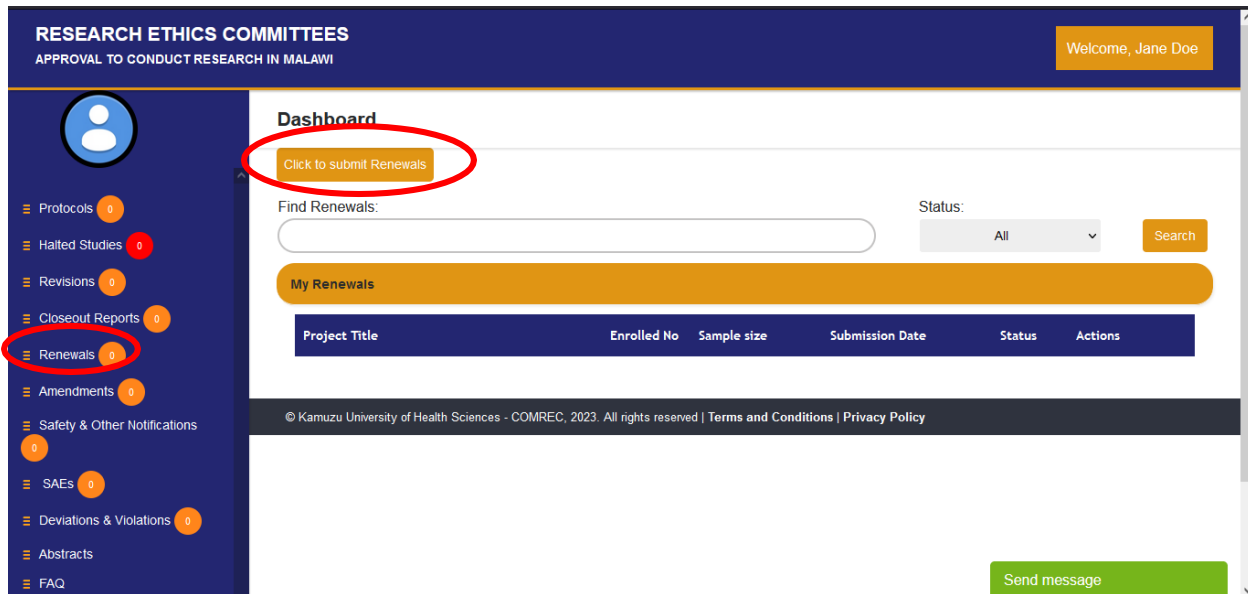
17. To make a Closeout Report, click on “Closeout Reports”, then “Click to submit Closeout Reports”



18. Then click on either “Already Online” or “Manual Submission” and proceed to submit your closeout report.

2.5 SUBMITTING RENEWALS

19.To submit a Renewal, click on “Renewals” and then, “Click to Submit Renewals”.



The screenshot displays the dashboard for the Research Ethics Committees (RECs) at Kamuzu University of Health Sciences. The header includes the text "RESEARCH ETHICS COMMITTEES" and "APPROVAL TO CONDUCT RESEARCH IN MALAWI", along with a user greeting "Welcome, Jane Doe". The left sidebar contains a navigation menu with items such as "Protocols", "Halted Studies", "Revisions", "Closeout Reports", "Renewals", "Amendments", "Safety & Other Notifications", "SAEs", "Deviations & Violations", "Abstracts", and "FAQ". The "Renewals" item is highlighted with a red circle. The main content area is titled "Dashboard" and features a "Click to submit Renewals" button, also highlighted with a red circle. Below this, there is a search bar labeled "Find Renewals:" and a "Status:" dropdown menu set to "All". A "My Renewals" section is visible, containing a table with columns for "Project Title", "Enrolled No", "Sample size", "Submission Date", "Status", and "Actions". At the bottom right, there is a "Send message" button.

20.Select either “Already online” or “Manual Submission” then proceed to fill in all the information.

Dashboard »Annual Renewal

Protocol Information

Status of Participants & Specimens

Literature & Challenges

Status of Future Plans/Activities

Payment

Select Protocol you are submitting to: *

Please Select Protocol

Brief rationale for the Study: *

General Research Objective: *

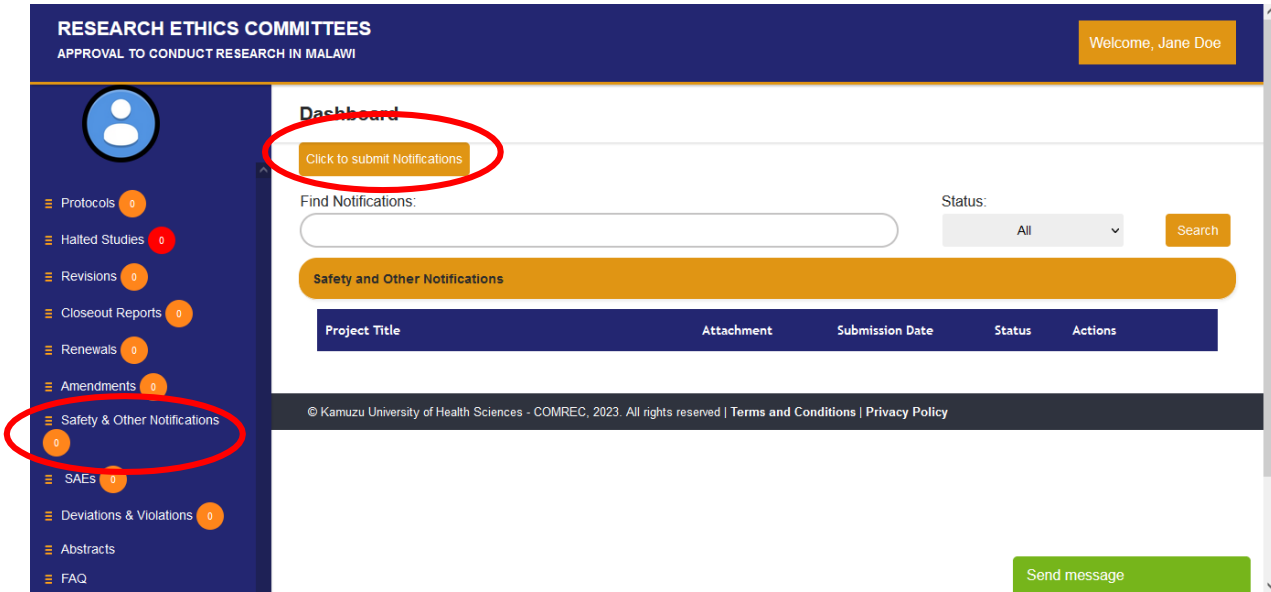
21. When you're done, click on "Save" and then "Renewals".

22. Your renewal will be added, and you can View, or edit it.

Project Title	Enrolled No	Sample size	Submission Date	Status	Actions
Test Drug	4	5	20/02/2020 10:46:50	Pending	+ View Submission + Edit Submission

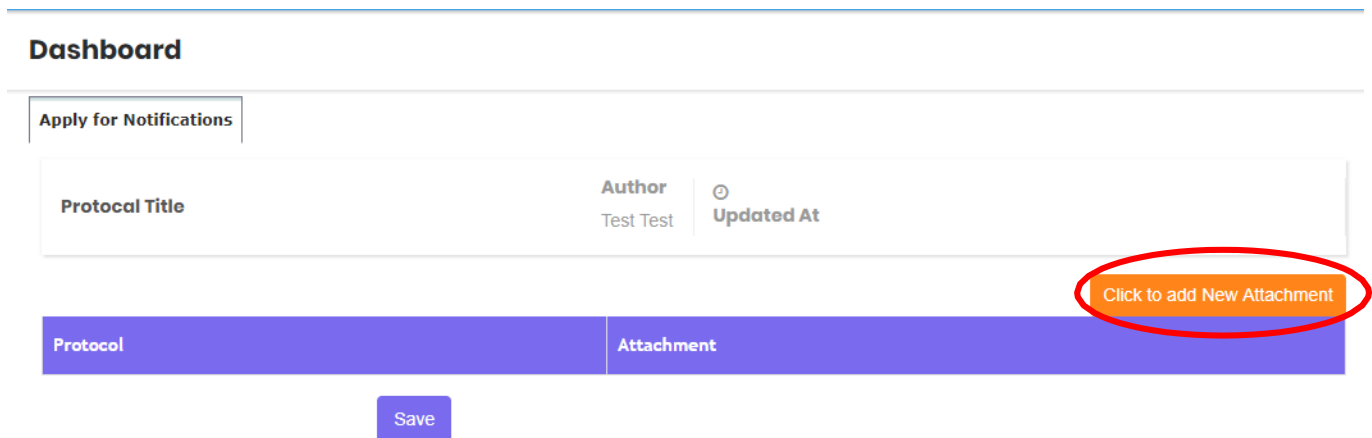
2.6 SUBMITTING SAFETY AND NOTIFICATIONS

23. To submit Safety and notifications, click on “Safety & other Notifications”, then “Click to Submit Notifications”.



The screenshot shows the 'RESEARCH ETHICS COMMITTEES' dashboard for 'APPROVAL TO CONDUCT RESEARCH IN MALAWI'. The user is logged in as 'Jane Doe'. The dashboard includes a sidebar with navigation items: Protocols (0), Halted Studies (0), Revisions (0), Closeout Reports (0), Renewals (0), Amendments (0), Safety & Other Notifications (0), SAEs (0), Deviations & Violations (0), Abstracts, and FAQ. The main content area is titled 'Dashboard' and features a 'Click to submit Notifications' button. Below this is a search bar for notifications and a 'Safety and Other Notifications' section with a table header: Project Title, Attachment, Submission Date, Status, and Actions. A footer contains copyright information for Kamuzu University of Health Sciences - COMREC, 2023, and a 'Send message' button.

24. Click “Click to add New Attachment”



The screenshot shows the 'Apply for Notifications' form. It includes a table with columns for 'Protocol Title', 'Author' (Test Test), and 'Updated At'. A 'Click to add New Attachment' button is highlighted in the bottom right corner. Below the table is a 'Save' button.

25. Select your protocol and upload the file. Then scroll down and click “Save”.

Dashboard

New Attachment

Select Protocol you are submitting to: *

Test Drug

File (PDF) *: Choose File No file chosen

26. Click “Save” to save it or “Make final Submission” to submit it.

Protocol Title Author Test Test Updated At

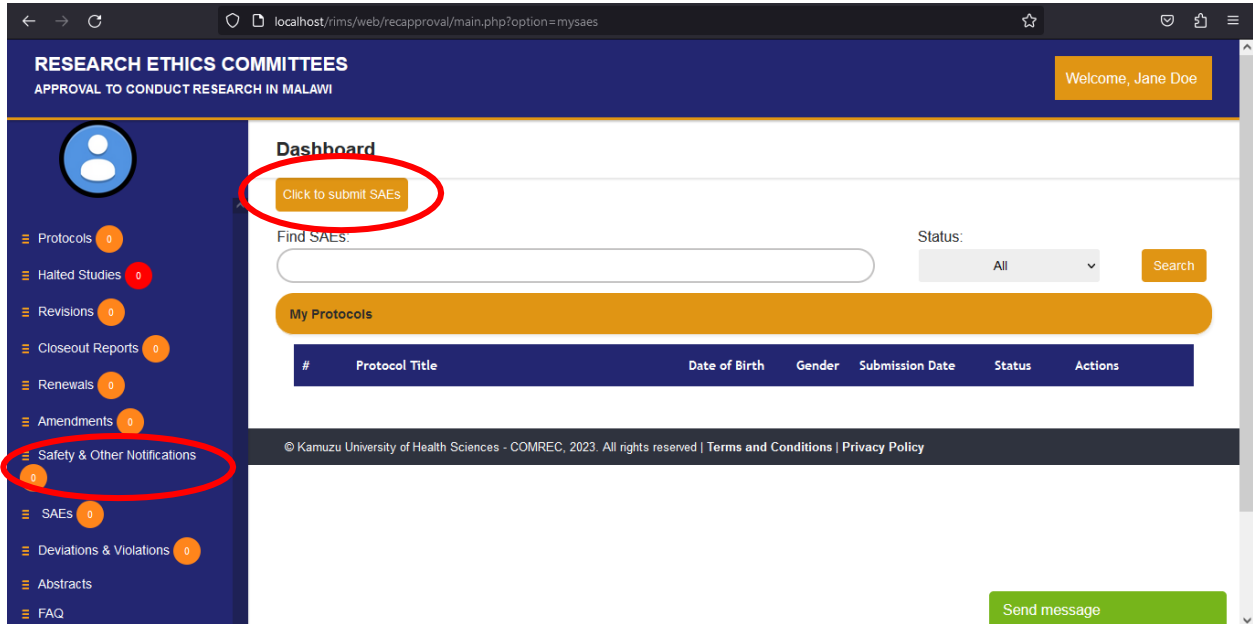
Changes have saved Click to add New Attachment

Protocol	Attachment
Test Drug	Click to view

Save Make Final Submission

2.7 APPLYING FOR SAEs

27. To submit SAEs, click on “SAEs”, then “Click to submit SAEs”



28. Fill in all the necessary information and click “Submit”

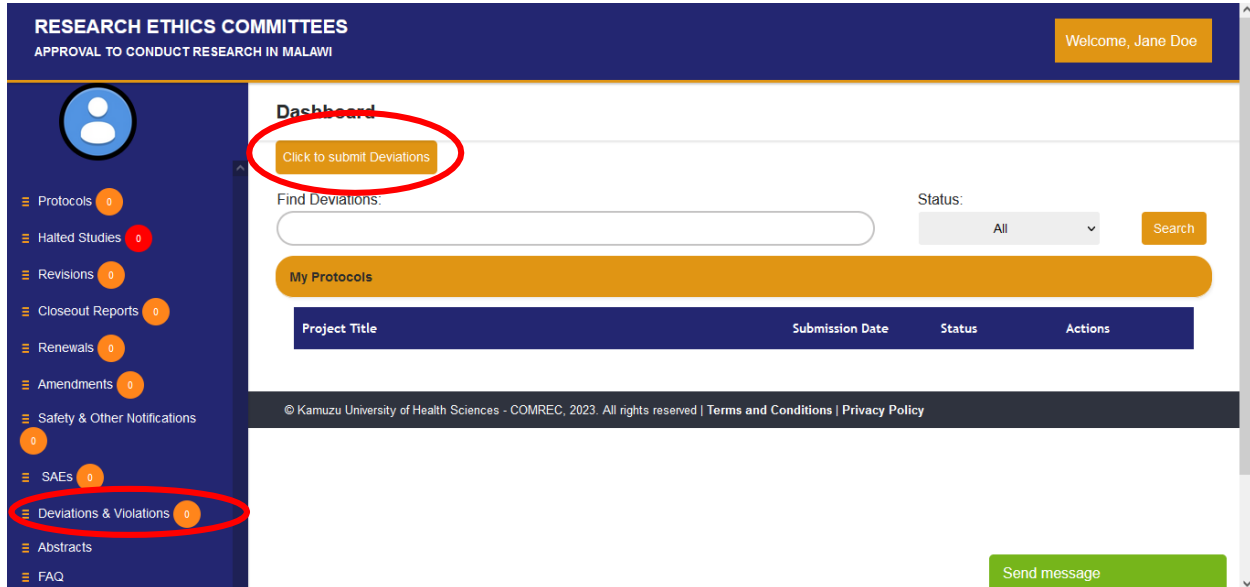
The screenshot shows a form for submitting an SAE. It features a text area labeled "Describe the corrective action undertaken *" with a character limit of 250 words. Below the text area is a file upload section labeled "Attach Evidence of corrective action (PDF only) *" with a "Choose File" button and the text "No file chosen". A "Submit" button is circled in red. A green "Online" button is visible in the bottom right corner.

29. A “Make Final Submission” button will then appear. Click on it to Submit.

The screenshot shows the same SAE submission form as in the previous image. The "Submit" button is now replaced by a "Make Final Submission" button, which is circled in red. The "Click to view" link is also visible below the file upload section.

2.8 SUBMITTING DEVIATIONS

30. To submit Deviations, click “Deviations & Violations”, then “Click to submit Deviations”



31. Fill in the necessary information and then click “Submit Details”

The screenshot shows a form for submitting a deviation. It features a large text area for entering details, with a character limit of 250 words. Below the text area is a section titled '5. Measures to mitigate violation' with a sub-section 'Measures (one per row)' containing a text input field and an 'Add More' button. At the bottom of the form, a blue 'Submit Details' button is circled in red.

32. A “Make Final Submission” Button will appear. Click on it to make submission.

This screenshot shows the same deviation submission form as above, but with an additional red 'Make Final Submission' button at the bottom, circled in red. The 'Submit Details' button is still present. The text area now contains the placeholder text 'QWERTYUI Delete'.

CHAPTER 3

3.1 CONCLUSION

In conclusion, protocol submissions are divided into subsections and reviewed accordingly by the REC. Depending on the information provided in the submission, your protocol can be approved, rejected, or approved conditionally, pending changes to certain aspects. It's crucial for users to exercise caution when entering their information, ensuring accuracy and completeness. All file attachments should be in **PDF format** with clear, descriptive names.

Additionally, you can conveniently track the status of your submission directly from your workspace. This allows you to quickly verify whether your protocol has been successfully submitted or if further action is required. You will have easy access to any comments or feedback provided by the REC, both within your workspace and through email notifications. Feedback letters generated by the system will also be available for your reference, providing valuable insights to guide you through the review process.

Remember to save your information at each stage before proceeding to ensure that changes are preserved and to streamline the submission process.