
NATIONAL RESEARCH INFORMATION MANAGEMENT SYSTEM (NRIMS)

**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 is an online platform that supports Kamuzu University of Health Sciences (COMREC).

The system provides efficient reviews of research and provides the researcher with an interface with COMREC in the data capture, data management, data validation, quality control and overall regulatory compliance to research management processes

1.2 GETTING STARTED

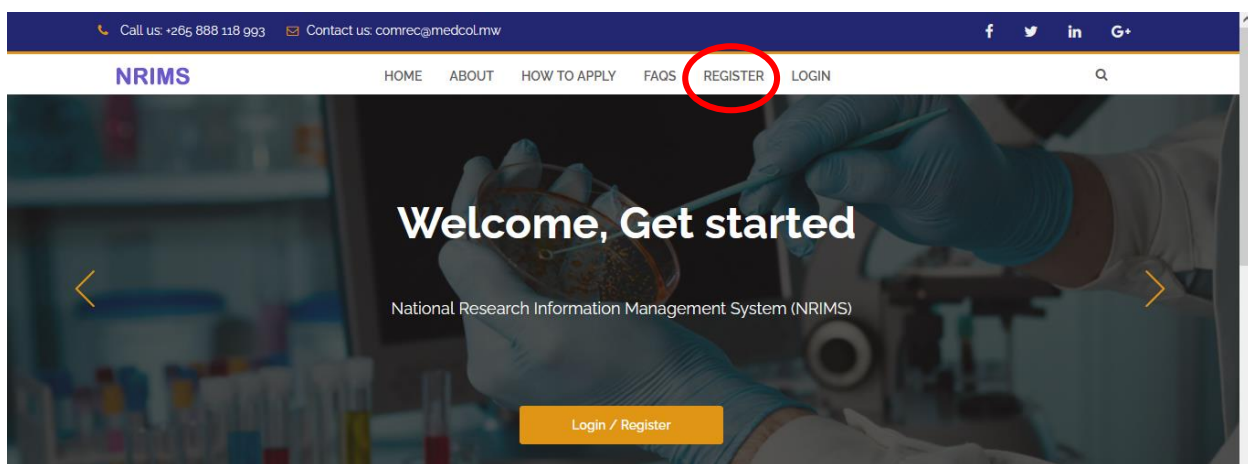
- To get started, access the NRIMS website on <https://rims.kuhs.ac.mw/>
- To create an account and submit a protocol, follow the steps in SECTION 2, Section 2.1
- After Submitting your protocol, it will be reviewed and feedback will be given through your registered email address.

CHAPTER 2

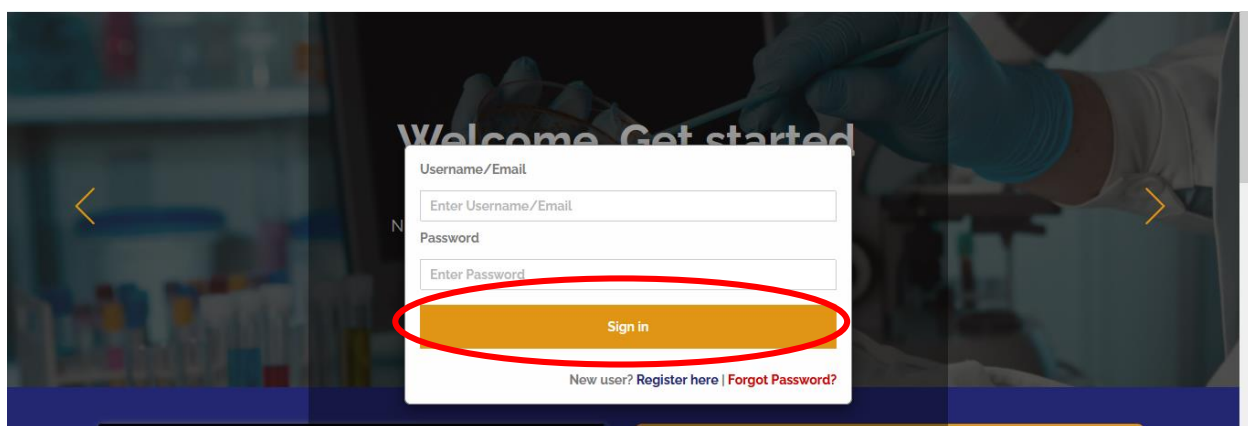
2.1 USING THE SYSTEM

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.

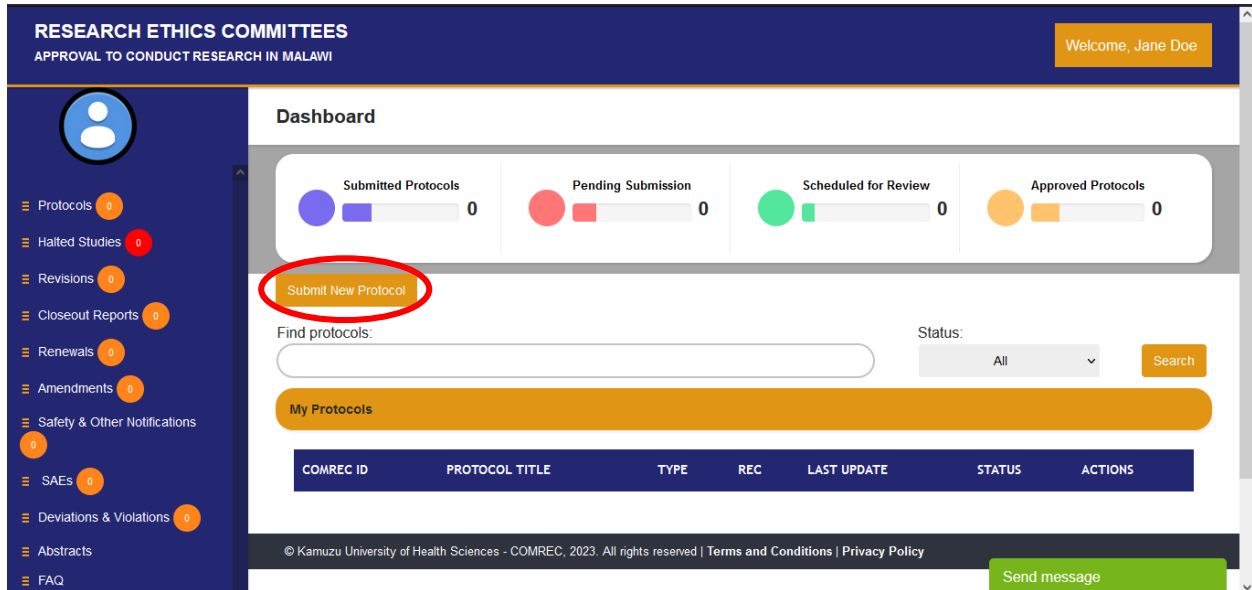
1. Click on “REGISTER” and fill in your information in all the required fields:



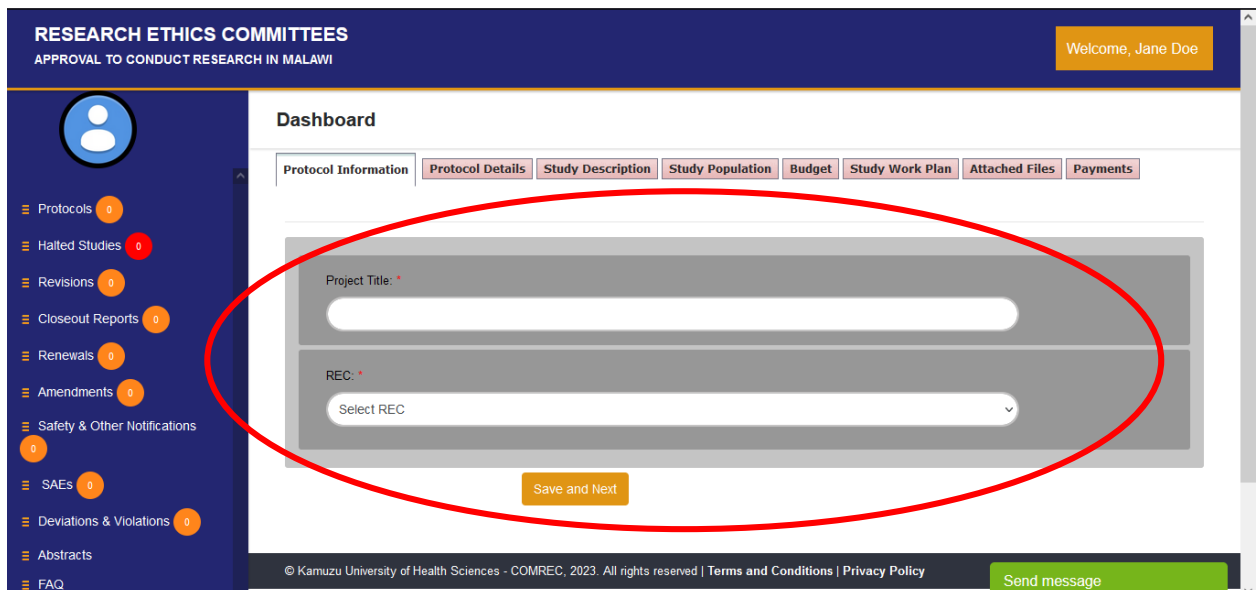
2. After registration, you will receive an activation email (Check your Junk/Spam folder if it's not in your inbox). Click on the activation link and you will be redirected to the home page, from here you can click on Login and fill in your username/email along with your password.



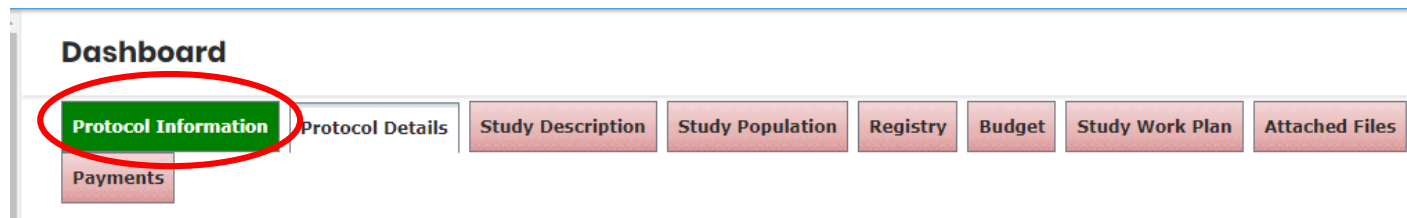
3. You will be logged in and taken to the Research Ethics Committees (REC) page. Click on “Submit New Protocol” to begin submitting your protocol information:



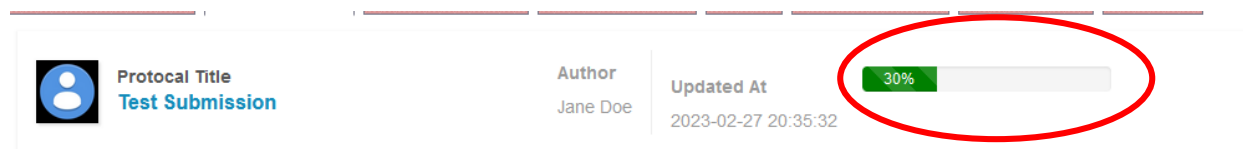
4. Begin by filling in the project title and select the REC you are submitting to then click “Save and Next”:



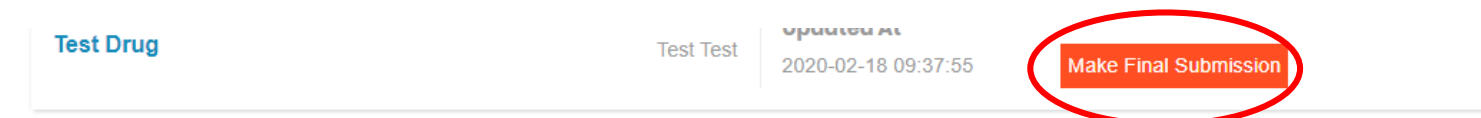
5. After filling in the required fields, the Protocol Information tab turns green, indicating completion of that section of your submission. If you proceed and a tab remains pink, this means that you have left out a certain section that needs to be filled on that tab.



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 edit after this point.



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

Status: All Search

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.

- If your protocol is rejected, in need of responses or gets a conditional approval by the REC, A button labeled “Update Submission” will appear and you will need to update your submission and resubmit your protocol.

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

- Update the necessary requirements and click “Resubmit” when done.



Protocol Title
NXT Tool

Author
Deng Luka

Updated At

100%

Resubmit

- After resubmission, you will be redirected back to the protocols menu and you can view or print your protocol as it gets reviewed again.

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 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 search bar for amendments, a 'My Protocols' section, and a sidebar with navigation options. The 'Amendments' option in the sidebar and the 'Apply for Amendments' button in the main content area are both circled in red.

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 :

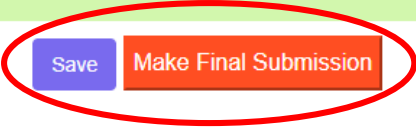
Online

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.

Dashboard

Find Ammendmnets: Status: All

My Protocols

Project Title	Type	Language	Version	Date	Status
Test Drug	Payment	English	6	2019-06-28	Submitted
	CoverLetter	English	9	2018-12-08	
	CleanCopy	English	9	2018-05-15	
	TrachedChanges	English	9	2018-05-12	

Online

2.4 MAKING A CLOSEOUT REPORT

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

RESEARCH ETHICS COMMITTEES
APPROVAL TO CONDUCT RESEARCH IN MALAWI

Welcome, Jane Doe

Dashboard

Click to submit Closeout Reports

Find Closeout Reports: Status: All

My Closeout Reports

Project Title	Attachment	Submission Date	Status	Actions
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Send message

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 (REC) 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 is a search bar labeled "Find Renewals:" and a "Status:" dropdown menu set to "All". A "My Renewals" section contains a table with columns for "Project Title", "Enrolled No", "Sample size", "Submission Date", "Status", and "Actions". The footer includes the copyright notice "© Kamuzu University of Health Sciences - COMREC, 2023. All rights reserved | Terms and Conditions | Privacy Policy" and 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 options: 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, 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 'Protocol Title' field, an 'Author' field with the value 'Test Test', and an 'Updated At' field. Below these fields is a table with two columns: 'Protocol' and 'Attachment'. A 'Click to add New Attachment' button is located at the bottom right of the table. A 'Save' button is positioned below the table.

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

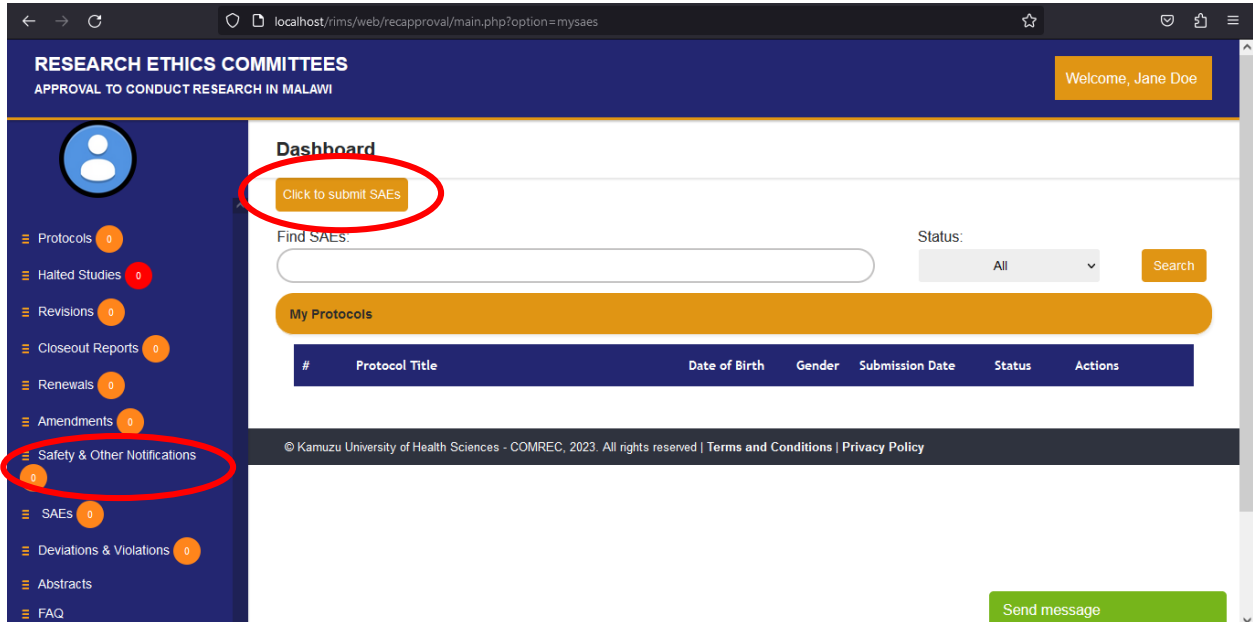
Protocol	Attachment
Test Drug	Click to view

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”

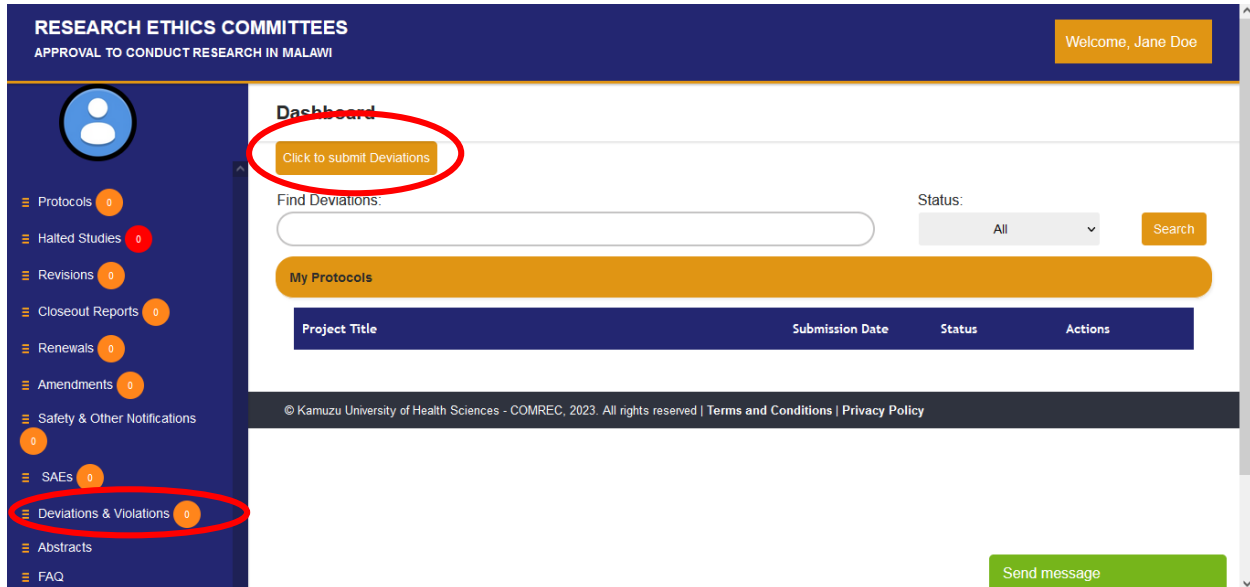
The screenshot displays a form for submitting a Safety Event Report (SAE). It features a text area labeled "Describe the corrective action undertaken *" with a character limit of 250 words. Below the text area is a file upload section for "Attach Evidence of corrective action (PDF only) *" with a "Choose File" button and the text "No file chosen". A blue "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.

This screenshot shows the same SAE submission form as above, but with an additional orange "Make Final Submission" button circled in red, appearing below the "Submit" button. The "Submit" button remains visible. The "Attach Evidence of corrective action" section now includes a "Click to view" link.

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 includes a large text area for description with a 'Characters limit: 250 words' warning. Below this 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 is a blue 'Submit Details' button.

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

This screenshot shows the same form as above, but with an additional orange 'Make Final Submission' button appearing at the bottom, next to the 'Submit Details' button. The text 'QWERTYUI Delete' is visible at the bottom left of the form area.

CHAPTER 3

3.1 CONCLUSION

Protocol Submissions are divided into sub sections and reviewed accordingly. Depending on the information provided in the submission, your protocol can be approved, rejected, or approved on a condition that a certain aspect of your protocol has to be changed.