University of Essex

Online

Section 2 Ethical approval

1. Consent

How do you intend to seek informed consent from participants?

An informed detailed consent form outlining the purpose of the research has been developed which outlines the procedures involved, potential risks, and benefits. The form includes information about confidentiality and data protection measures, ensuring participants understand their rights, including the right to withdraw from the study at any time without penalty.

2. Right to withdraw

How do you intend to inform participants of their right to withdraw?

The participants will be informed about their right to withdraw within the informed consent form. The section reads like below;

You have the right to withdraw from this study at any time without any negative consequences or impact on your current status. If you decide to withdraw, please inform Francis Muwalo on +265 888 208 986, or email **muwalofra@gmail.com** . Your data will be removed from the study, and any collected information will not be used in the research analysis.

Also, we intend to inform the participants during the study on their right to withdraw. The data collection documentation will also inform them about this to ensure that they fully understand and willingly participating.

3. Confidentiality

How do you intend to maintain confidentiality?

All data collected during the research will be anonymized to ensure that individual participants cannot be identified. There will be no collection of patient data. Identifiable information will be removed or obscured before analysis.

Access to data will be controlled through secure passwords and permissions.

Physical Records will be kept in locked cabinets in secure areas, with access restricted to authorized personnel.

After the study, digital files will be permanently deleted, and physical records will be securely shredded.

4. Harm

How do you intend to protect participants from harm?

This study will not handle patient data. To ensure participant protection from harm, the research will implement several measures. Confidentiality and anonymity will be maintained by anonymizing data and securing it with encryption and passwords, accessible only to authorized personnel. Participants will receive detailed informed consent, outlining the study's nature, potential risks, benefits, and their right to withdraw without penalty. Risks will be minimized by allowing participants to skip uncomfortable questions. The study will undergo ethical review by the University ethics committee. Data handling will comply with GDPR and local data protection laws. Participation will be entirely voluntary, and the research team will be trained in ethical practices.

5. Data access, storage and security

Please confirm that all personal data will be stored and processed in compliance with the General Data Protection Regulation (GDPR). Describe the arrangements for storing and maintaining the security of any personal data collected as part of the project.

This study will not collect any personal or patient data. All data collected will be stored and processed in compliance with the General Data Protection Regulation (GDPR). Data will be encrypted and protected by passwords, access-controlled, and stored on secure computers, with physical copies kept in locked cabinets. Identifiable information will be separated from research data to ensure anonymity. Only authorized research team members will have access to the data, which will be retained only as long as necessary and then securely deleted. Participants will be informed of their rights under GDPR, including the right to access, correct, and delete their data.

6. Other issues

Identify any specific ethical issues relating to this research, for example if your research involves vulnerable groups like young children, or pupils who have SEND (special educational needs/disability).

Since this research focuses on assessing and designing processes for TB tracking rather than directly involving patients or their data, specific ethical issues include ensuring accuracy and integrity in evaluating and designing systems, respecting stakeholder input by considering healthcare workers' feedback, and avoiding conflicts of interest by disclosing and managing any potential conflicts to maintain research integrity.

Section 3 Risk Assessment

If your research does not involve human participants, you are able to enter "N/A" in the comment box.

1. Are there any potential risks, for example physical, psychological, social, legal or economic, to participants or subjects associated with the proposed research?

YES

Please provide full details of the potential risks and explain what risk management procedures will be put in place to minimise the risks:

Participants may not open up and give accurate information when discussing challenges faced in their current workflows.

There could be concerns about sharing critical feedback regarding current systems, which might affect data gathering.

To mitigate these risks, participants will be assured of confidentiality and the voluntary nature of their involvement, with the option to withdraw at any time without consequences. Make sure that the data collection tools are clear and easy to understand.

2. Are there any potential risks to researchers as a consequence of undertaking this proposal?

YES

Please provide details and explain what risk management procedures will be put in place to minimise this.

Data collection will depend on external parties and may not be available on time which can affect the project delivery. This can be mitigated by proper project planning, ensuring that data is collected early and we have a backup plan for data collection.

Licencing of some tools used for the project. We have ensured that the licences are already in place to mitigate this risk.

3. Are there any potential reputational risks to the University of Essex Online as a consequence of undertaking this proposal?

NO

Please provide full details and explain what risk management procedures will be put in place to minimise this.

4. Will the research involve individuals below the age of 18 or individuals of 18 years and over with a limited capacity to give informed consent?

NO

(If yes, a Disclosure and Barring Service disclosure (DBS check) may be required. Please attach as part of your application). Give further details of participants below.

5. Are there any other ethical issues that have not been addressed, which you would wish to bring to our attention?

No

Give details below:

Section 4 Confirmation Statements

The results of research should benefit society directly or by generally improving knowledge and understanding. I confirm that my research project has a potential benefit to Malawi by improving the current TB tracking challenges through the system that will be developed after analysing the current challenges. This will benefit the patient in the long run.

I confirm that I have read the Research Ethics Policy and the relevant sections of the Research Ethics Procedures and will adhere to these in the conduct of this project.

Signature

Date and Signature space are available in the form.