ANNEXURE Q - RESEARCH ETHICS APPLICATION FOR NQF 8 RESEARCH REPORTS & UNDERGRADUATE RESEARCH PROJECTS

The IIE subscribes to the Belmont Report, Singapore Statement, Human Sciences Research Council (HSRC) and Human Research Ethics Requirements as set out by the South African Department of Health as guidelines for ethical research practice. These reports highlight the three core principles of respect for persons, beneficence, and justice as critical when considering ethical clearance or consent. Carefully consider your request from an ethics perspective before you submit. The Research and Postgraduate Studies Policy (IIE007) can be found on either the institutional website (external candidates) or Tertiary Hub (IIE Staff) and provides a clear outline of the ethics position of The IIE. The IIE's Campus Research Ethics Committee has the right to withhold any research that is not aligned with the institutional policies and best practices of ethical research.

1. UNDERGRADUATE PROGRAMMES.

The following documents must be submitted to your lecturer for research ethics clearance:

- Research proposal or Research Plan
- Data collection instrument or the Primary or Secondary Research Technique (such data collection instrument or justification for sources from where document for content analysis will be sourced from).
- Informed consent forms/ research cover letter that will be shared with participants or respondents.
- Annexure G (b) –Research Ethics Consent Application (IIE007) if your data sample are IIE students, staff, artefacts, or systems.

2. PGDIP PROGRAMMES..

The following documents must be submitted to your lecturer for research ethics clearance:

- Research proposal or Research Plan
- Data collection instrument or Primary or Secondary Research Technique (such data collection instrument or justification for sources from where document for content analysis will be sourced from).
- Informed consent forms/ research cover letter that will be shared with participants or respondents.
- Annexure G (b) –Research Ethics Consent Application (IIE007) if your data sample are IIE students, staff, artefacts, or systems.

3. 4-YEAR BACHELOR DEGREES; HONOURS, PGDIP IN DATA ANALYTICS, AND PGDIP HIGHER EDUCATION:

The following documents must be submitted to your supervisor/ lecturer for research ethics clearance:

- Research proposal or Research Plan
- Data collection instrument or research Primary or Secondary Research Technique (such data collection instrument or justification for sources from where document for content analysis will be sourced from).
- Informed consent forms/ research cover letter.
- Annexure G (b) –Research Ethics Consent Application (IIE007) if your data sample are IIE students, staff, artefacts, or systems.

PROCESS FOR NQF8 ETHICS CLEARANCE:

- The supervisor/ lecturer are responsible for ensuring that the student under their supervision completes Annexure Q and meet the required Research Ethics Clearance requirements as documented in the IIE007 Policy, Procedure and Criteria and Standards document.
- The supervisor/ lecturer reviews the Research Ethics Clearance application and submit to the Postgraduate Academic Lead or Postgraduate Programme Coordinator who will issue the Research Ethics Clearance letter.
- The Research Ethics Clearance letter must be signed by both the Postgraduate Academic Lead or Postgraduate Programme Coordinator and the supervisor/ lecturer.
- If a supervisor/ lecturer is not comfortable with research ethics application meeting the required ethical standards of the IIE007 Policy, they may request the Postgraduate Academic Lead or Postgraduate Programme Coordinator to setup an ad hoc Campus Research Ethics Meeting with at least two experienced supervisors to review the ethics application and provide an outcome.
- The Postgraduate Academic Lead or Postgraduate Programme Coordinator will ensure that all annexures and signed letters are uploaded on the Postgraduate Research Tracker.
- It remains the responsibility of the supervisor/ lecturer to ensure that students do not collect data until they have received their research ethics clearance letter.

Student Details												
Title	Prof	☐	Dr	☐	Ms	☐	Mrs	☐	Mr	☒	Mx	☐
First name(s)	Makabongwe Lwethu											
Last name(s)	Sibisi											
Title of study	Closing the Gap Between Lab and Clinic: Validating Lightweight AI for ECG Arrhythmia Classification											
Qualification	Postgraduate Diploma in Data Analytics											

Supervisor Details												
Title	Prof	☒	Dr	☐	Ms	☐	Mrs	☐	Mr	☐	Mx	☐
First and last names	Mohammed Vawda											

Co-supervisor Details (if applicable)												
Title	Prof	☐	Dr	☐	Ms	☐	Mrs	☐	Mr	☐	Mx	☐
First and last names												

Explaining your research process						
Philosophical paradigm	Positivism	☒	Interpretivism	☐	Constructivism	☐
	Realism	☐	Objectivism	☐	Pragmatism	☐
	Functionalist	☐	Subjectivism	☐	Humanist	☐
	Other:					
Research design:	Interview	☐	Questionnaire (self administered)	☐	Focus group	☐
	Ethnography/ Observation	☐	Artefact analysis/website/ social media analysis	☐	Action Research	☐
	Case Study	☐	Design Research (Practice based)	☐		☐
	Other *(if so, state)*	☒	Retrospective Computational Experiment			

Ethics		
Documentation submitted with proposal	Gatekeeper's letter (institutional consent if research done at institutions other than IIE)	☐
	Completed Annexure G (b) –Research Ethics Consent Application Form (IIE007) if your data sample are IIE students, staff, artefacts, or systems.	☐
	Data Collection Instruments for primary data collection such as interview schedules, observation sheet, questionnaire, or focus group questions.	☐
	Informed Consent Form / Research Cover Letter (applicable for primary data collection) • For self-administered questionnaires include informed consent/ cover letter as part of the cover page of the questionnaires	☐

Applicants should apply the below ethical considerations to their research and explain how the ethical areas of consideration will be covered in the research.

<table>
<tr><th>AREA</th><th>DETAIL</th><th>RESPONSE PROVIDED BY THE APPLICATION ON EACH OF THE CATEGORIES.</th></tr>
<tr><td>Provide a brief background of the Study and Introduction</td><td colspan="2">Cardiovascular diseases are the leading global cause of death, with arrhythmias posing a diagnostic challenge in resource-limited settings. While deep learning models show promise in automating ECG classification, most lack clinical robustness and generalizability. This study aims to develop and externally validate a lightweight AI model (RDSCNN) to assist clinicians in accurate arrhythmia classification under real-world conditions.</td></tr>
<tr><td rowspan="3">Brief explanation of the participant sample and population</td><td>Select the sampling technique to be used and explain in the next column
Purposive ☐ Random ☐ Snowball ☐
Convenient ☐ Stratified ☐ Census ...
No under 18’s or vulnerable groups allowed.</td><td rowspan="2">- ECG signals representing diverse patients with various arrhythmias.
- Purposive sampling from MIT-BIH Arrhythmia Database and PTB Diagnostic ECG Database</td></tr>
<tr><td>The rationale for the inclusion and exclusion of participants must be clear, explicit and reasonable. Clearly indicate the intended number of participants and the average time they will be required of them to participate. If vulnerable participants are to be included, an adequate justification should be provided; protective safeguards and measures should be explained. Inclusion and exclusion criteria, recruitment and the means of getting consent all have ethical implications (e.g. fairness of selection) over and above their impact on generalisability and validity.</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Briefly describe the research procedures</td><td colspan="2">The research procedure involves accessing and preprocessing public ECG datasets through noise filtering, heartbeat segmentation, and AAMI-compliant annotation mapping. Subsequently, the RDSCNN model is developed, trained, and hyperparameter-tuned. Validation adheres strictly to the inter-patient paradigm and AAMI standards. Performance is evaluated using metrics including accuracy, F1-score, sensitivity, and computational efficiency (inference time, parameters, FLOPs).</td></tr>
<tr><td>Explain the data Collection Instrument or Technique</td><td>Briefly describe the method(s) that will be used to collect data from participants. If it is through interviews, then interview questions need to be submitted; if it is through survey, the survey questions need to be submitted along with the application. If you conduct observational research, action research or content analysis please explain the process of collecting data. For desktop studies, justify the sources from which information will be gathered to answer the research question. Should you be using any alternative method of data collection not mentioned, please provide details on the instrument used or technique to source the data.</td><td>The study utilizes publicly available, expert-annotated ECG datasets (MIT-BIH, PTB Diagnostic) as primary instruments. These datasets were selected for their clinical relevance (validated in peer-reviewed research), accessibility/ standardization (enabling benchmarking and reproducibility), and diversity (spanning varied patient demographics and arrhythmia types). Data processing employs Python libraries (wfdb, NumPy, Pandas) for signal handling, while model training and analysis are implemented using TensorFlow/Keras frameworks.</td></tr>
<tr><td>Reimbursements, inducements & costs for participants</td><td>If there are going to be any inducements (including refunds of costs) for participation these need to be examined for the impact on the data and procedure.</td><td>N/A</td></tr>
<tr><td>Participants’ privacy & confidentiality interests</td><td>Privacy and confidentiality protecting mechanisms must be stated and must be adequate. The means of protecting the data throughout the study and afterwards must be explicitly stated. If there are conditions that may result in a researcher violating confidentiality (such as if abuse is uncovered) this must be stipulated. POPI provisions must be explicitly dealt with including consent from an appropriate person for minors or other vulnerable groups.</td><td>N/A</td></tr>
<tr><td>Obtaining informed consent</td><td>Detail on how the informed consent will be gained must be made clear including how any risk of pressure or influence will be eliminated. This process must detail what information is provided to the potential participant and how it covers all the</td><td>N/A</td></tr>
</table>

	participant needs to know to make a truly informed decision. The consent letter must fully align to the information detailed in the proposal in relation to consent. It must include details about how the data is being stored and what methods are to be used such as recording. If you collect data through a self-administered questionnaire (such as Google Forms, MS Forms, Survey Monkey, etc.) it's important to include the informed consent letter/ cover letter as part of the questionnaire on Page 1 with a tick box. Once the respondent selects the textbox, they can complete the questionnaire. Also ensure that you include screening that aligns with your target sample selection as indicated earlier.	

N/A

N/A

Declaration by the Student
1. All the statements made by myself in this application are true and accurate. 2. I am bound by the requirements of ethical and sound research practices. 3. I will obtain informed consent in writing from all participants after disclosing all the information that would be needed to give this consent. 4. I will only use this data for these research purposes and in no other way. 5. I will protect the anonymity, confidentiality and privacy of participants and associated institutions or structures. 6. I will only use recording methods (written, audio, video) consented to and in the manner consented to. 7. I will meet all conditions set and not proceed until I have authorisation to do so.

	13 / 06 / 2025
Signature of the Student	**Date**

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Supervisor's Recommendation to the Campus Ethics Committee:
Proposal has been reviewed by the supervisor and necessary ethics considerations have been included. ☐ **Accepted with no conditions**. ☐ **Accepted with conditions:** *Provide the nature of the condition that the student needs to consider*: e.g. Instrument is not sufficient / included and need to be signed off by the supervisor ☐ **Ethics Clearance Withheld:** Student is not allowed to commence with data collection. *Provide the reason for withholding the ethics approval and provide the necessary action points that the student needs to consider for the resubmission for ethics clearance.* Click or tap here to enter text.

Notes from the Supervisor	
	Signature and date
Notes from Postgraduate Academic Lead or Postgraduate Programme Coordinator	
	Signature and date