UNIVERSITY OF WESTMINSTER

University Research Ethics Committee
Front cover sheet for applications

Applicant's name: Hammadh Yusuf Mohamed Arquil

Project Title: Health Status Assessment in Remote Patient Monitoring Systems using Hybrid Machine Learning

Application Reference ___ - ___ - ___ **(for office use only)**

Please complete the checklist below before submitting your ethics application

Enclosed:	**YES**	**NO**	**N/A**
Application Form Part A attached.	☑	☐	☐
Application Form Part B attached (if applicable).	☐	☐	☑
Any external ethical approval (copy of application and approval letter) attached.	☐	☑	☐
Draft Participant Information Sheet attached (see available exemplars).	☐	☑	☐
Draft Informed Consent Form attached (see available exemplars).	☐	☑	☐
Draft Indicative Questions, e.g. questionnaire(s), proposed interview questions or questioning areas, etc. attached.	☐	☑	☐
Appropriate risk assessments have been completed, e.g. Control of Substances Hazardous to Health (COSHH), Radiation, etc. (if applicable) – *Contact the University's Safety, Health and Wellbeing Team for advice on this and other aspects of health and safety.*	☐	☑	☐
Fieldwork Risk Assessment attached (if applicable). *(UCEA Guidance on Health and Safety in Fieldwork Including offsite visits and travel in the UK and overseas) – Contact the University's Safety, Health and Wellbeing Team for advice on this and other aspects of health and safety.*	☐	☑	☐
Travel Insurance Request clearance notification attached (if applicable). *Contact - Andrew Clarke (a.clarke03@westminster.ac.uk) or Alison Sylvestre (a.sylvestre@westminster.ac.uk) in Procurement if advice is required – This is essential if there is any Foreign and Commonwealth Office or RED24 advice against travel.*	☐	☑	☐
Confirmation of Insurance coverage for research undertaken off campus.	☐	☑	☐
Security-sensitive research assessment completed (if applicable) and uploaded (see UniversitiesUK Guidance and, if applicable, complete the Annex to Part B and upload).	☐	☑	☐
Other (please specify, e.g. letters from collaborators, etc.):	☐	☑	☐

_____

Applicant's signature: 

Date: 1st November 2022

Supervisor's signature: 

Date: 1st November 2022

OFFICE USE: ___ - ___-_____

University of Westminster
University Research Ethics Committee

Application for Research Ethics

PART A

Section 1 – PROJECT AND APPLICANT DETAILS

1.1 **Project Title:** Health Status Assessment in Remote Patient Monitoring Systems using Hybrid Machine Learning

1.2 **Applicant Details**

Name: Hammadh Yusuf Mohamed Arquil	**University Email Address:** w1761780@my.westminster.ac.uk
Contact Address: 627/10 Peradeniya Road Kandy, Sri Lanka	**Telephone Number: +94** 762462721
Faculty: Computing	

Please check the relevant box:

Undergraduate ☑ **Postgraduate** ☐ **MPhil/PhD Student** ☐ **Staff** ☐

I confirm I have read the *University's Code of Practice Governing the Ethical Conduct of Research*	**YES** ☑	**NO** ☐

1.3 Supervisor/Dean of Faculty/Faculty Research Director details

Please note that all applicants with a supervisor(s) must ensure that the supervisor signs the declaration at the bottom of this page if completing Part A only or in **Section 10.3** if completing Part B

All **staff** must ensure that their Dean of Faculty, or Faculty Research Director (or nominee), as appropriate, signs the declaration at the bottom of this page if completing Part A only or in **Section 10.3** if completing Part B

Name: Divya Premanantha	**University Email Address:** divya.p@iit.ac.lk
Faculty: Computing	**Telephone Number:** -

PART A

Section 2 – Project Details

2.1 Please provide a description of the background with references to relevant literature (250 words maximum): Remote Patient Monitoring allows healthcare providers to view and monitor patient health information remotely from a distance and provide necessary steps to prevent the patient from deteriorating further, however, this requires manual assessment of the patient's health status and alerts only when the vital signs of a patient hit the threshold values. Meanwhile available solutions to counter this have come with several performance issues due to the nature of the data used in training their solutions.

2.2. Please provide a brief description and the aims of your study (250 words maximum): The aim of this study is to conduct research in the design, development and evaluation of a novel hybrid machine learning model to be used in the overall health criticality risk status of a patient using a Remote Patient Monitoring system.

2.3. Please outline the design and methodology of your study (include details of the selection and recruitment of participants (if any) and details of any invasive (e.g. blood samples, inhalation/ingestion of food and/or non-food products (in abnormally higher or lower levels than normal or a different form), or intrusive (e.g. questionnaires, focus groups, interviews, etc.) procedures [attach extra information as necessary] (400 words maximum in total): The study plans to use the MIMIC dataset provided by MIT however this requires credentialed access and the author had undergone training certification in human subjects research, however, the data that would actually be used would not require any ethical clearance due to its nature of being vital signs to train the model. Any questionnaires and interviews conducted will solely be for feedback on the systems architecture and not related to the data collected.

2.4. Timescales
Start Date (DD/MM/YY): 01/10/22
Estimated duration of work: 8 Months

Section 3 - RISK OF HARM

NOTE 1: Where indicated below applicants should check if the research will require ethical approval from a National Research Ethics Committee via the Integrated Research Application System (IRAS) - nres.queries@nhs.net.- http://www.hra-decisiontools.org.uk/ethics/
NOTE 2: The University of Westminster holds a Human Tissue Authority Licence – This licence is specifically for tissue stored at 115 New Cavendish Street in accordance with the terms of the licence – Advice must be obtained from the University Human Tissue Designated Individual (N.Presneau@westminster.ac.uk)

	RISK OF HARM (to self, colleagues, participants, environment or animals)	**Yes**	**No**	**N/A**
1	Will any pain or more than mild discomfort result from the study?	☐	☑	☐
2	Could the study induce any psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☑	☐
3	Will the study involve prolonged or repetitive physical or psychological testing of human participants that may put someone at risk, e.g. use of treadmill?	☐	☑	☐
4	Will the study involve raising sensitive topics (e.g. sexual activity, drug use, revelation of medical history, bereavement, illegal activities, etc.)?	☐	☑	☐
5	Does your work involve any "relevant material" containing human cells (e.g. blood, urine, saliva, body tissues but NOT established cell-lines) from living or deceased persons (Such work must take account of the Human Tissue Act)? – See Note 1 and 2 above.	☐	☑	☐
6	Will DNA samples be taken from human participants (Such work must take account of the Human Tissue Act)? – See Note 1 and 2 above.	☐	☑	☐
7	Does your study raise any issues of personal safety for you or other researchers or participants involved in the project (Especially relevant if taking place outside working hours or off University premises)?	☐	☑	☐
8	Does your study involve deliberately misleading the participants (e.g. deception, covert observation)?	☐	☑	☐
9	Does your work involve administration of a food or non-food substance of a different type from or in abnormally higher or lower amounts than normal or one that is known to cause allergic reaction(s) or potential psychological stress?	☐	☑	☐
10	Does your study involve issues relating to personal and/or sensitive data?	☐	☑	☐
	PARTICIPANTS (and/or their records/associated data) **Does your work involve any of the following:**	**Yes**	**No**	**N/A**
11	Human participants in a health and/or social care setting (e.g. patients, those attending day centres, community care, rehabilitation centres, etc., including in the NHS, other public, private and/or voluntary sectors)? – See Note 1 above.	☐	☑	☐
12	Human participants who may be deemed vulnerable (e.g. children, people in poverty and/or with physiological or psychological impairments, persons attending rehabilitation centres, persons in easily identifiable positions that could be subject to victimisation, etc.)?	☐	☑	☐
13	Expectant or new mothers?	☐	☑	☐
14	Refugees/Asylum seekers?	☐	☑	☐
15	Minors (under the age of 18 years old)?	☐	☑	☐
16	Participants in custody (e.g. prisoners or arrestees)? – See Note 1 above.	☐	☑	☐
17	Participants with impaired mental capacity (e.g. severe mental illness, brain damage, sectioned under Mental Health Act, lowered or reduced sense of consciousness)? – See Note 1 above.	☐	☑	☐
18	Animals (or animal tissue).	☐	☑	☐
	INFORMATION TO PARTICIPANTS	**Yes**	**No**	**N/A**
19	Will you provide participants with a Participant Information Sheet prior to obtaining informed consent which can be taken away by the participant?	☑	☐	☐
20	Will you describe the procedures to participants in advance, so that they are informed about what to expect?	☑	☐	☐
21	Will you obtain informed consent for participation (normally written)? OR in the case of using personal data previously acquired was consent given for the reuse of the data for other research purposes?	☑	☐	☐
22	Will you tell participants that they may withdraw from the research at any time and for any reason without any impact on their care, service provision etc.?	☑	☐	☐
23	Will you give participants the option of omitting questions they do not want to answer?	☑	☐	☐
24	Will you tell participants that their data will be treated as confidential and that, if published, it will not be identifiable as theirs?	☑	☐	☐
25	Will you offer feedback to participants at the end of their participation, upon request (e.g. give them a brief explanation of the study and its outcomes)?	☑	☐	☐

26	Has external funding or collaboration been applied for/received, which requires institutional ethical consideration or approval?	☑	☐	☐

Useful links:

- http://www.screc.org.uk/ - Social Care Research Ethics Committee
- http://www.hra-decisiontools.org.uk/ethics/ - Human Research Authority decision tool to identify if research needs National Research Ethics Committee approval
- http://www.nres.nhs.uk/applications/guidance/governance-and-directives/?entryid62=131341 – Governance Arrangements for Research Ethics Committees
- http://www.nres.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=134016 - NRES algorithm "Does my project require review by a Research Ethics Committee"?
- http://www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm - Human Tissue Authority Code of Practice
- http://www.hta.gov.uk – Human Tissue Authority website
- http://www.rsclearn.mrc.ac.uk/MRC_HumanTissueAct/player.html - Medical Research Council online training course for Human Tissue Act.

What to do next:

- **If you have answered NO to questions 1-18 (inclusive) and YES to questions 19-25 (inclusive)**, you do not need to complete the Full Research Ethics Approval Form (Part B). Please keep this form for your records, and do not submit to **Faculty Research Ethics Committee** (FREC) unless you require ethical consideration of your study, regardless of ethical implications, by an external body (question 26 has been answered YES). **A list of Faculty contacts is below.**

- **If you have answered YES to any of the questions 1-18 (inclusive) or NO to any of the questions 19-25** the Full Research Ethics Approval Form (Part B) MUST be submitted including Cover Sheet, Part A and Part B of the application form plus any required supplementary documents to the Secretary of the relevant Faculty Research Ethics Committee (FREC). **A list of Faculty contacts is below.**

- If you are applying for external Ethical Approval, please send a *copy* of the Conditions/Approvals letters to the **University Research Ethics Committee** (UREC) Secretary (this may include the original ethical application(s)). Where the external ethics committee/body has equal standing or primary jurisdiction, e.g. another University Research Ethics Committee or a National Research Ethics Committee, any approval will normally be received and noted by the University of Westminster Research Ethics Committee and further consideration may not be required. Where the external committee does not have equal or higher standing than the University Committee then the full ethical approval process at the university may still be required. Additional institutional compliance issues may need consideration by UREC.
- All Applications (dated, signed and authorised) and supplementary information or External Approvals should be sent to the University Research Ethics Committee (UREC) Secretary in *electronic format with a version number, document name and date and the Principal Investigator (or Undergraduate/Postgraduate Taught Student) name. On receipt your application will be issued a unique reference number*
- All new Applications should be submitted to a Research Ethics Committee (FREC or UREC) Secretary a minimum of 10 working days in advance of the Committee meeting date (earlier submission is recommended so that applications can be pre-vetted and obvious issues addressed before the application is considered by the Committee).

Contact details:

Faculty	Chair	Secretary
Architecture and the Built Environment	Professor Nick Bailey	**Colette Davis**
Media Arts and Design	Dr Anthony Mcnicholas	**Fauzia Ahmad**
Science and Technology	**Dr John Colwell**	**Mandy Walton**
Science and Technology Psychology Department Sub Committee	**Dr Laura Boubert**	**TBC**

Faculty	Chair	Secretary
Social Sciences and Humanity	Professor Marco Roscini	**Victoria Grey-Edwards**
Westminster Business School	**Petar Sudar**	**Haydn Worley**
University Research Ethics Committee	**Professor Graham Megson**	**Huzma Kelly**

For Use in Academic Year: 2015/16

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