Prifysgol Cymru
Y Drindod Dewi Sant
University of Wales
Trinity Saint David

PG2 / E1 FORM

APPLICATION FOR ETHICAL APPROVAL

RESEARCH STUDENTS This form is to be completed by the student within **SIX** months for full-time students and **TWELVE**months for part time students, after the commencement of the research degree orfollowing progression to Part Two of your course. Once complete, submit this form via the ***MyTSD Doctoral College Portal*** at (https://mytsd.uwtsd.ac.uk). This document is also available in Welsh.
RESEARCH STAFF ONLY All communications relating to this application during its processing must be in writing and emailed to pgresearch@uwtsd.ac.uk , with the title 'Ethical Approval' followed by your name.
STUDENTS ON UNDERGRADUATE OR TAUGHT MASTERS PROGRAMMES should submit this form (and receive the outcome) via systems explained to you by the supervisor/module leader.

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. A researcher may not be covered by the University's insurance if ethical approval has not been obtained prior to commencement.

The University follows the OECD Frascati manual definition of **research activity**: "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications". As such this covers activities undertaken by members of staff, postgraduate research students, and both taught postgraduate and undergraduate students working on dissertations/projects.

The individual undertaking the research activity is known as the "principal researcher".

Ethical approval is not required for routine audits, performance reviews, quality assurance studies, testing within normal educational requirements, and literary or artistic criticism.

Please read the notes for guidance before completing ALL sections of the form.

This formmust be completed and approved prior to undertaking any research activity. Please see Checklist for details of process for different categories of application.

SECTION A: About You (Principal Researcher)

1	Full Name:		Anjaliben Tusharbhai Vora			
2	Tick all boxes that apply:		Member of staff:	☐	Honorary research fellow:	☐
	Undergraduate Student	☐	Taught Postgraduate Student	☐	Postgraduate Research Student	✓

3	Institute/Academic Discipline/Centre:	University of Wales trinity Saint David
4	Campus:	London
5	E-mail address:	2221529@student.uwtsd.ac.uk
6	Contact Telephone Number:	07767945104
	For students:	

7	Student Number:	2221529
8	Programme of Study:	Msc in public Health and Social Care in Practice
9	Director of Studies/Supervisor:	Dr. Diola Bijlhout

SECTION B: Approval for Research Activity

1	Has the research activity received approval in principle? (please check the Guidance Notes as to the appropriate approval process for different levels of research by different categories of individual)	**YES**	☐	**NO**	✓
				Date	
2	If Yes, please indicate source of approval (and date where known):***Approval in principle must be obtained from the relevant source prior to seeking ethical approval***	Research Degrees Committee	☐	N/A	
		Institute Research Committee	☐	N/A	
		Other (write in)	☐	N/A	

SECTION C: Internal and External Ethical Guidance Materials

	Please list the core ethical guidance documents that have been referred to during the completion of this form (including any discipline-specific codes of research ethics, location-specific codes of research ethics, and also any specific ethical guidance relating to the proposed methodology). Please tick to confirm that your research proposal adheres to these codes and guidelines. You may add rows to this table if needed.	
1	**UWTSD Research Ethics & Integrity Code of Practice**	✓
2	**UWTSD Research Data Management Policy**	✓
3	*[List any other relevant documents here]*	N/A

SECTION D: External Collaborative Research Activity

If there are external collaborators then you should gain consent from the contact persons to share their personal data with the university. If there are no external collaborators then leave this section blank and continue to section E.

1	Institution	N/A				
2	Contact person name	N/A				
3	Contact person e-mail address	N/A				
4	Is your research externally funded?		**YES**	☐	**NO**	✓
5	Are you in receipt of a KESS scholarship?		**YES**	☐	**NO**	✓
6	Are you specifically employed to undertake this research in either a paid or voluntary capacity?	Voluntary	**YES**	☐	**NO**	✓
7		Employed	**YES**	☐	**NO**	✓
8	Is the research being undertaken within an existing UWTSD Athrofa Professional Learning Partnership (APLP)?	If YES then the permission question below does not need to be answered.	**YES**	☐	**NO**	✓

9	Has permission to undertake the research has been provided by the partner organisation?	(If YES attach copy) If NO the application cannot continue	**YES**	☐	**NO**	✓

Where research activity is carried out in collaboration with an external organisation

10	Does this organisation have its own ethics approval system?	**YES**	☐	**NO**	✓
	If Yes, please attach a copy of any final approval (or interim approval) from the organisation (this may be a copy of an email if appropriate).				

SECTION E: Details of Research Activity

1	Indicative title:	Analysing the long-term impact of wearable fitness tracker on public health metrics utilised by fitness seekers (aged Group 20- 65 years old) and healthcare professionals.		
2	Proposed start date:	30/10/2023	Proposed end date:	17/01/2024
	Introduction to the Research (maximum 300 words per section) **Ensure that you write for a <u>Non-Specialist Audience</u> when outlining your response to the points below:** *Purpose of Research Activity* *Proposed Research Question* *Aims of Research Activity* *Objectives of Research Activity* Demonstrate, briefly, how **<u>Existing Research</u>** has informed the proposed activity and explain *What the research activity will add to the body of knowledge* *How it addresses an area of importance.*			
3	**Purpose of Research Activity** The purpose of the research activity is to analyse impacts of wearable in healthcare that allows patients to take charge of their health data in real-time with health metrics of monitoring heart rate, blood oxygen, stress, hydration, respiratory rate, into account targeting specific health professionals and adults aged 20 to 65 years.			
4	**Research Question** What are the long-term impacts of wearable fitness trackers on public health metrics as used by healthcare professionals and fitness seekers (age 20 to 65 years)?			

5	**Aims of Research Activity** The aim of the research is to shed light on the significance of the implementation of wearble fitness tracker users on specific health professionals and adults aged 20 to 65 undertaking health metrics of monitoring heart rates, blood oxygen, stress management, hydration and respiratory rate.
6	**Objectives of Research Activity** • To analyse the advent of wearable in significant advancement of tracking and fitness-related data on specific health professionals and adults aged between 20 to 64 years. • To assess the effectiveness of wearable fitness tracker users on specific health specilist and adults aged 20 to 65 years for monitoring heart rate, blood oxygen, stress, hydration, respiratory rate.
	Proposed methods (maximum 600 words) Provide a brief summary of all the methods that **may** be used in the research activity, making it clear what specific techniques may be used. If methods other than those listed in this section are deemed appropriate later, additional ethical approval for those methods will be needed. You do not need to justify the methods here, but should instead describe how you intend to collect the data necessary for you to complete your project.
7	A high-quality systematic review is described as the most reliable source of evidence to guide clinical practice. The goal of a systematic review is to provide a thorough summary of all the primary research available to answer a research question (Clarke, 2011). Systematic review is a method in which there are wider chances to get information from various sources and databases as compared to primary research. Moreover, ethics will be upheld during systematic review by considering common forms of database bias, citation bias, language bias and multiple publication bias. With its theoretical freedom, thematic analysis provides a highly flexible approach that can be modified according to the needs of multiple studies, providing a rich and detailed yet complex account of the data (Nowell et al., 2017). Furthermore, for this methodology, different databases will be used as instruments such as google scholar, Pubmed, Cochrane library, Science library, University library. **Limitations** • Conducting a systematic review may be a time-consuming process, and the body of evidence may change before the study is finished. • Language bias may be introduced into systematic reviews since they frequently only include research published in a certain language. It is possible to overlook important studies that have been published in other languages.
	Location of research activity Identify all locations where research activity will take place.
8	N/A

	Research activity outside of the UK If research activity will take place overseas, you are responsible for ensuring that local ethical considerations are complied with and that the relevant permissions are sought. Specify any local guidelines (e.g. from local professional associations/learned societies/universities) that exist and

	whether these involve any ethical stipulations beyond those usual in the UK (provide details of any licenses or permissions required). Also specify whether there are any specific ethical issues raised by the local context in which the research activity is taking place, for example, particular cultural and/or legal sensitivities or vulnerabilities of participants. If you live in the country where you will do the research then please state this.

References

Clarke, J. (2011). What Is a Systematic review? Evidence-Based Nursing, 14(3), pp.64–64. doi:https://doi.org/10.1136/ebn.2011.0049.

Nowell, L.S., Norris, J.M., White, D.E. and Moules, N.J. (2017). Thematic analysis: Striving to Meet the Trustworthiness Criteria. International Journal of Qualitative Methods, 16(1), pp.1–13. doi:https://doi.org/10.1177/1609406917733847.

9	The research will also utilise researches on Canadian private and public hospitals under "Canadian Copyright Act of 1921" for ethical considerations in the protection of data and authorised collection of information from authentic sources.

10	Use of documentation not in the public domain: Are any documents **NOT** publicly available?	**NO**	✓
		YES	☐
11	If Yes, please provide details here of how you will gain access to specific documentation that is not in the public domain and that this is in accordance with the current data protection law of the country in question and that of England and Wales. *(this box should expand as you type)*		

	Does your research relate to one or more of the seven aims of the Well-being of Future Generations (Wales) Act 2015?	**YES**	**NO**
12	A prosperous Wales	☐	✓
13	A resilient Wales	☐	✓
14	A healthier Wales	✓	
15	A more equal Wales	☐	✓
16	A Wales of cohesive communities	☐	✓
17	A Wales of vibrant culture and thriving Welsh language	☐	✓
18	A globally responsible Wales	☐	✓
19	If YES to any of the above, please give details:		
	The research on long-term impact of wearable fitness tracker users on public health metrics for healthcare professionals and household fitness seekers forecasts the incorporation of "Well-being of Future Generations (Wales) Act 2015" for mental and physical well-being of society and benefitting the future health.		

SECTION F: Scope of Research Activity

	Will the research activity include:	**YES**	**NO**
1	Use of a questionnaire or similar research instrument?	☐	✓
2	Use of interviews?	☐	✓
3	Use of focus groups?		✓
4	Use of participant diaries?	☐	✓
5	Use of video or audio recording?	☐	✓
6	Use of computer-generated log files?	☐	✓
7	Participant observation with their knowledge?	☐	✓
8	Participant observation without their knowledge?	☐	✓

9	Access to personal or confidential information without the participants' specific consent?	☐	✓
10	Administration of any questions, test stimuli, presentation that may be experienced as physically, mentally or emotionally harmful / offensive?	☐	✓
11	Performance of any acts which may cause embarrassment or affect self-esteem?	☐	✓
12	Investigation of participants involved in illegal activities?	☐	✓
13	Use of procedures that involve deception?	☐	✓
14	Administration of any substance, agent or placebo?	☐	✓
15	Working with live vertebrate animals?	☐	✓
16	Procedures that may have a negative impact on the environment?	☐	✓
17	Other primary data collection methods. Please indicate the type of data collection method(s) below.		
	Details of any other primary data collection method: (this box should expand as you type)	☐	✓

If NO to every question, then the research activity is (ethically) low risk and **may** be exempt from **some** of the following sections (please refer to Guidance Notes).

If YES to any question, then no research activity should be undertaken until full ethical approval has been obtained.

SECTION G: Intended Participants

If there are no participants then do not complete this section, but go directly to section H.

	Who are the intended participants:	**YES**	**NO**
1	Students or staff at the University?	☐	✓
2	Adults (over the age of 18 and competent to give consent)?	☐	✓
3	Vulnerable adults?	☐	✓
4	Children and Young People under the age of 18? (Consent from Parent, Carer or Guardian will be required)	☐	✓
5	Prisoners?	☐	✓
6	Young offenders?	☐	✓
7	Those who could be considered to have a particularly dependent relationship with the investigator or a gatekeeper?	☐	✓
8	People engaged in illegal activities?	☐	✓
9	Others. Please indicate the participants below, and specifically any group who may be unable to give consent.		
	Details of any other participant groups: (this box should expand as you type)	☐	✓

	Participant numbers and source Provide an estimate of the expected number of participants. How will you identify participants and

	how will they be recruited?	
10	How many participants are expected?	N/A *(this box should expand as you type)*
11	Who will the participants be?	N/A *(this box should expand as you type)*
12	How will you identify the participants?	N/A *(this box should expand as you type)*

	Information for participants:	**YES**	**NO**	**N/A**
13	Will you describe the main research procedures to participants in advance, so that they are informed about what to expect?	☐		✓
14	Will you tell participants that their participation is voluntary?	☐		✓
15	Will you obtain written consent for participation?	☐		✓
16	Will you explain to participants that refusal to participate in the research will not affect their treatment or education (if relevant)?	☐		✓
17	If the research is observational, will you ask participants for their consent to being observed?	☐		✓
18	Will you tell participants that they may withdraw from the research at any time and for any reason?	☐		✓
19	With questionnaires, will you give participants the option of omitting questions they do not want to answer?	☐		✓
20	Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	☐		✓
21	Will you debrief participants at the end of their participation, in a way appropriate to the type of research undertaken?	☐		✓
22	If NO to any of above questions, please give an explanation			
	(this box should expand as you type)			

	Information for participants:	**YES**	**NO**	**N/A**
24	Will participants be paid?	☐		✓
25	Is specialist electrical or other equipment to be used with participants?	☐		✓
26	Are there any financial or other interests to the investigator or University arising from this study?	☐		✓
27	Will the research activity involve deliberately misleading participants in any way, or the partial or full concealment of the specific study aims?	☐		✓
28	If YES to any question, please provide full details			
	(this box should expand as you type)			

SECTION H: Anticipated Risks

	Outline any anticipated risksthat may adversely affect any of the participants, the researchers and/or the University, and the steps that will be taken to address them. If you have completed a full risk assessment (for example as required by a laboratory, or external research collaborator) you may append that to this form.		
1	**Full risk assessment completed and appended?** **N/A**	**Yes**	☐
		No	☐
2	**Risks to participants** For example: sector-specific health & safety, emotional distress, financial disclosure, physical harm, transfer of personal data, sensitive organisational information		
	Risk to participants: **N/A** *(this box should expand as you type)*	*How you will mitigate the risk to participants:* **N/A** *(this box should expand as you type)*	
3	If research activity may include sensitive, embarrassing or upsetting topics (e.g. sexual activity, drug use) or issues likely to disclose information requiring further action (e.g. criminal activity), give details of the procedures to deal with these issues, including any support/advice (e.g. helpline numbers) to be offered to participants. Note that where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities		
	N/A *(this box should expand as you type)*		
4	**Risks to the investigator** For example: personal health &safety, physical harm, emotional distress, risk of accusation of harm/impropriety, conflict of interest		
	Risk to the investigator: **N/A** *(this box should expand as you type)*	*How you will mitigate the risk to the investigator:* **N/A** *(this box should expand as you type)*	
5	**University/institutional risks** For example: adverse publicity, financial loss, data protection		
	Risk to the University: **N/A** *(this box should expand as you type)*	*How you will mitigate the risk to the University:* **N/A** *(this box should expand as you type)*	
6	**Environmental risks** For example: accidental spillage of pollutants, damage to local ecosystems		
	Risk to the environment: **N/A** *(this box should expand as you type)*	*How you will mitigate the risk to environment:* **N/A** *(this box should expand as you type)*	

	Disclosure and Barring Service			
	If the research activity involves children or vulnerable adults, a Disclosure and Barring Service (DBS) certificate must be obtained before any contact with such participants.	**YES**	**NO**	**N/A**
7	Does your research require you to hold a current DBS Certificate?	☐	✓	☐

8	If YES, please give the certificate number. If the certificate number is not available please write “Pending”; in this case any ethical approval will be	**N/A**

	subject to providing the appropriate certificate number.	N/A

SECTION I: Feedback, Consent and Confidentiality

1	**Feedback** What de-briefing and feedback will be provided to participants, how will this be done and when?
	N/A *(this box should expand as you type)*
2	**Informed consent** Describe the arrangements to inform potential participants, before providing consent, of what is involved in participating. Describe the arrangements for participants to provide full consent before data collection begins. If gaining consent in this way is inappropriate, explain how consent will be obtained and recorded in accordance with prevailing data protection legislation.
	N/A *(this box should expand as you type)*
3	**Confidentiality / Anonymity** Set out how anonymity of participants and confidentiality will be ensured in any outputs. If anonymity is not being offered, explain why this is the case.
	N/A *(this box should expand as you type)*

SECTION J: Data Protection and Storage

	Does the research activity involve personal data (as defined by the General Data Protection Regulation 2016 "GDPR" and the Data Protection Act 2018 "DPA")?	**YES**	**NO**
1	***"Personal data"****means any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Any video or audio recordings of participants is considered to be personal data.*		✓
	If YES, provide adescription of the data and explain why this data needs to be collected:		
2	.N/A		
	Does it involve special category data (as defined by the GDPR)?	**YES**	**NO**
3	***"Special category data"*** *means sensitive personal data consisting of information as to the data subjects' –* *(a) racial or ethnic origin,* *(b) political opinions,* *(c) religious beliefs or other beliefs of a similar nature,* *(d) membership of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),* *(e) physical or mental health or condition,* *(f) sexual life,* *(g) genetics,* *(h) biometric data (as used for ID purposes),*		✓

	If YES, provide adescription of the special category data and explain why this data needs to be collected:
4	N/A

	Will data from the research activity (collected data, drafts of the thesis, or materials for publication) be stored in any of the following ways?	**YES**	**NO**
5	Manual files (i.e. in paper form)?		✓
6	University computers?		✓
7	Private company computers?		✓
8	Home or other personal computers?		✓
9	Laptop computers/ CDs/ Portable disk-drives/ memory sticks?		✓
10	"Cloud" storage or websites?		✓
11	Other – specify:		✓
12	For all stored data, explain the measures in place to ensure the security of the data collected, data confidentiality, including details of backup procedures, password protection, encryption, anonymisation and pseudonymisation:		
	Whole research activity will be store in personal computer. *(this box should expand as you type)*		

	Data Protection		
	Will the research activity involve any of the following activities:	**YES**	**NO**
13	Electronic transfer of data in any form?		✓
14	Sharing of data with others at the University outside of the immediate research team?	☐	✓
15	Sharing of data with other organisations?	☐	✓
16	Export of data outside the UK or importing of data from outside the UK?		✓
17	Use of personal addresses, postcodes, faxes, emails or telephone numbers?	☐	✓
18	Publication of data that might allow identification of individuals?		✓
19	Use of data management system?		✓
20	Data archiving?		✓
21	If YESto any question, please provide full details, explaining how this will be conducted in accordance with the GDPR and Data Protection Act (2018) (and any international equivalents, where appropriate):		
	N/A		
22	List all who will have access to the data generated by the research activity:		
	N/A		

23	List who will have control of, and act as custodian(s) for, data generated by the research activity:		
	N/A		
24	Give details of data storage arrangements, including security measures in place to protect the data, where data will be stored, how long for, and in what form. Will data be archived – if so how and if not why not.		
	N/A		
25	Please indicate if your data will be stored in the UWTSD Research Data Repository (see https://researchdata.uwtsd.ac.uk/). If so please explain. (*Most relevant to academic staff)*		
	The research will incorporate data from UWTSD Research Data Repository in order to incorporate the systematic literature review through real-life case examples and authentic data.		
26	Confirm that you have read the UWTSD guidance on data management (see https://www.uwtsd.ac.uk/library/research-data-management/)	**YES**	✓
27	Confirm that you are aware that you need to keep all data until after your research has completed or the end of your funding	**YES**	✓

SECTION K: Declaration

	The information which I have provided is correct and complete to the best of my knowledge. I have attempted to identify any risks and issues related to the research activity and acknowledge my obligations and the rights of the participants. In submitting this application I hereby confirm that I undertake to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice which is published on the website: https://www.uwtsd.ac.uk/research/research-ethics/		
1	**Signature of applicant:**	ANJALIBEN TUSHARBHAI VORA	**Date:26/10/2023**

For STUDENT Submissions:

2	Director of Studies/Supervisor:		**Date:**
3	Signature:		

For STAFF Submissions:

4	Academic Director/ Assistant Dean:		**Date:**
5	Signature:		

Checklist: Please complete the checklist below to ensure that you have completed the form according to the guidelines and attached any required documentation:

✓	I have read the guidance notes supplied before completing the form.
✓	I have completed **ALL RELEVANT** sections of the form in full.
✓	I confirm that the research activity has received approval in principle
✓	I have attached a copy of final/interim approval from external organisation (**where appropriate**)
✓	I have attached a full risk assessment (where appropriate)*ONLY TICK IF YOU HAVE **ATTACHED A FULL RISK ASSESSMENT***
✓	I understand that it is my responsibility to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice.
✓	I understand that before commencing data collection all documents aimed at respondents (including information sheets, consent forms, questionnaires, interview schedules etc.) must be confirmed by the DoS/Supervisor, module tutor or Academic Director.

RESEARCH STUDENTS ONLY Once complete, submit this form via the **MyTSD Doctoral CollegePortal** at (https://mytsd.uwtsd.ac.uk).
RESEARCH STAFF ONLY All communications relating to this application during its processing must be in writing and emailed to pgresearch@uwtsd.ac.uk , with the title 'Ethical Approval' followed by your name.
STUDENTS ON UNDERGRADUATE OR TAUGHT MASTERS PROGRAMMES should submit this form (and receive the outcome) via systems explained to you by the supervisor/module leader.