UNIVERSITY ETHICS COMMITTEE

GUIDANCE ON SUBMITTING FORMS

SEPTEMBER 2021

OVERVIEW OF PROCESS

- The ethical approval process is a means by which the University seeks to ensure that all researchers consider carefully the ethical implications of their research activity.
- Each academic discipline should establish a procedure to ensure the processes below are followed.
- All ethical approval applications are completed on the form **PG2-E1**.
  - Located in "complete list of forms" link on forms tab of the HWB.

10 COMMON SHORTCOMINGS

1. Section B:
   - Omitting date
2. Section B:
   - Omitting name of the staff member and their designated role
3. Section C:
   - Not citing external guidance correctly
4. Section D:
   - Indicating 'Yes' when 'No' may be more appropriate.
     - *This does not normally apply to university placement experiences which are part of the students' programme of study e.g. schools, youth organisations, observational placements*
     - *In these cases you would indicate 'No'*

10 COMMON SHORTCOMINGS

5. Section E:
   - Ensure that the proposed start date is **after** the Committee Ethics meeting
6. Section F:
   - Any boxes ticked should be commented upon in the methodology (section E)
7. Section G:
   - Give number of participants and say how you will identify participants
8. Section H:
   - **All** research carries risk
     - Ensure that risks are identified
     - Do not put 'Not Applicable'
9. Section J:
   - Personal Data is ticked No when Personal Data will be collated.
   - Not an accurate reflection of the data storage and data protection considerations.
10. Section K:
    - Include date of signature and tick relevant boxes on checklist.

FURTHER GENERAL OBSERVATIONS

- Section C and E:
  - Reference should be made to ethics guidance outside the UK
- Section E:
  - Under 'location of research activity' it is up to the discretion of the supervisor in conversation with the student as to whether the name of an organisation is included
  - Word count in relation to each sub section of section E – stick to the guidelines.
- Section G:
  - Ensure that you tick one the boxes either **'YES', 'NO'** or **N/A**

FURTHER GENERAL OBSERVATIONS

- Section H:
  - ‘Applicant needs to consider an honest reflection and consideration of the risks and how to mitigate them.
- Section I:
  - Make explicit reference to how feedback (debriefing), informed consent, confidentiality and anonymity will be achieved
- Section J:
  - Electronic transfer of data means communicating data between electronic devices e.g. one database to another. It also relates to transcribing text from an electronic recording device to a computer.
  - Under ‘list all who have access to the data generated by the research activity..’ this applies to raw data and you should consider carefully who should access this.
  - Ensure that you provide details if boxes are ticked
- At the end of the form, do not include the Application Process.

SECTION A

This should be a straight forward section, but make sure it is completed accurately.

SECTION A: About You (Principal Researcher)

1	Full Name:					
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:	
4	Campus:	
5	E-mail address:	
6	Contact Telephone Number:	
	For students:	
7	Student Number:	
8	Programme of Study:	
9	Director of Studies/Supervisor:	

SECTION B

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*** ***source***	Research Degrees Committee	☐		
		Institute Research Committee	☐		
		Other (write in)	☐		

Include Name of Staff Member and their Designated Role

Put in Date

SECTION C

Now default to include UWTSD Codes of Ethical Practice – Although you must check this.

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]*	☐

Please note we would be FULLY expecting you to also note additional ethical guidance materials (e.g. BPS) and cite this accordingly.

SECTION D

Ticking 'Yes' when 'No' may be more appropriate. This does not normally apply to university placement experiences which are part programme of study e.g. schools, youth organisationsof the students', observational placements.
In these cases you would tick **'No'.**

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					
2	Contact person name					
3	Contact person e-mail address					
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	☐

SECTION E (SLIDE 1)

Ensure that the proposed start date is **AFTER** the Committee Ethics meeting

SECTION E: Details of Research Activity

1	Indicative title:			
2	Proposed start date:		Proposed end date:	
	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** (this box should expand as you type)			
4	**Research Question** (this box should expand as you type)			

Use research to provide background to the research area

Research question and any hypotheses should be in this section

SECTION E (SLIDE 2)

	(this box should expand as you type)
5	**Aims of Research Activity** (this box should expand as you type)
6	**Objectives of Research Activity** (this box should expand as you type)
	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	(this box should expand as you type)

Aims and Rationale in this box

Potential Research Implications here – and summarise the aims

Important – this is the methods – design, materials and procedure should be here.

SECTION E (SLIDE 3)

	Location of research activity Identify all locations where research activity will take place.

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8	(this box should expand as you type)
	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.
9	*(this box should expand as you type)*

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)*		

As it says provide details of the location here – be truthful

Document details if the research is taking place outside of the UK provide details of ethical stipulations of that location

If you are using documentation NOT in the public domain then you must detail here.

SECTION E (SLIDE 4)

	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:		
	(this box should expand as you type)		

If you research relates to one or more of the 7 aims of the Well-being of Future Generations (Wales) Act – then check according above and give details here (point 19).

SECTION F

Any boxes ticked **YES** should be commented upon in the Methodology (Section E)

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)	☐	☐

SECTION G (SLIDE 1)

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)	☐	☐

Just complete honestly – remember to check NO if it is NO – don't leave blank.

	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?	(this box should expand as you type)
11	Who will the participants be?	(this box should expand as you type)
12	How will you identify the participants?	(this box should expand as you type)

Note the number of participants (approx.), the type of participant (e.g. Uni students?) and how you are going to obtain the participants here.

SECTION G (SLIDE 2)

You shouldn't really be ticking "NO" to any of these questions

	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)			

You shouldn't really be ticking "YES" to any of these questions

	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 (SLIDE 1)

All research, if it involves participants carries risk to the participant and investigator. Ensure that risks are identified

Do not put **'Not applicable'**

Please Note – No Word Count Limit in Section H

Left hand column you note the risks – right hand column you report how you will mitigate the risks

SECTION H: Anticipated Risks

	Outline any anticipated risks that 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?**	**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: *(this box should expand as you type)*	*How you will mitigate the risk to participants:* *(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		
	(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: *(this box should expand as you type)*	*How you will mitigate the risk to the investigator:* *(this box should expand as you type)*	

SECTION H (SLIDE 2)

All research, if it involves participants carries risk to the University / Institute Ensure that risks are identified

Do not put **'Not applicable'**

Please Note – No Word Count Limit in Section H

Environmental Risks – This is study specific and if your research has the potential of environmental risks then you need to acknowledge it.

We are aware that not all research has an environenmental risk so, in these situations, you can place N/A.

5	**University/institutional risks** For example: adverse publicity, financial loss, data protection	
	Risk to the University: *(this box should expand as you type)*	*How you will mitigate the risk to the University:* *(this box should expand as you type)*
6	**Environmental risks** For example: accidental spillage of pollutants, damage to local ecosystems	
	Risk to the environment:	*How you will mitigate the risk to environment:*

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	(this box should expand as you type)	*(this box should expand as you type)*

SECTION H (SLIDE 3)

	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 subject to providing the appropriate certificate number.			

Disclosure and Barring Service (DBS) – If your research requires for you to hold a DBS then you must answer this section.

SECTION I

Researchers are required to indicate in the ethics form that they will follow the Ethical policy within their place of work/placement, to provide a letter which demonstrates the organizations support for the research, in addition consent forms given to all participants and if this work involves minors (under 18 in line with UWTSD) that parents/guardians are also asked for their consent.

Make explicit reference to HOW and WHEN Feedback and Debriefing will be given to the participants.

Make explicit reference to HOW informed consent will be achieved

Make explicit reference to HOW confidentiality and anonymity will be achieved

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?
	(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.
	(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.
	(this box should expand as you type)

SECTION J (SLIDE 1)

Section J refers to the Type and storage of your data. It is important that you have a good understanding of GDPR (2016) and the DPA (2018) and tick honestly if your data COULD potentially contain personal and special category data (see description). You then need to explain if yes, the description of the data and WHY you need to collect this data.

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 a description of the data and explain why this data needs to be collected:		
2	*(this box should expand as you type)*		

	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 a description of the special category data and explain why this data needs to be collected:		
4	*(this box should expand as you type)*		

SECTION J (SLIDE 2)

	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:		
	(this box should expand as you type)		

Please note this is for all stored data.

SECTION J (CONTINUED)

Answer this section truthfully – Electronic Transfer of Data is especially common in research.

	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?	☐	☐

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21	If YES to 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):
	(this box should expand as you type)

SECTION J (CONTINUED)

This **ONLY** applies to **RAW DATA** and you should consider carefully who should have access
Normally this would be the researcher and supervisor but in placement contexts, this could also be a leader or designated person. In some cases an external examiner might ask for access to raw data.

Regarding storage of Raw data, make sure you are adhering the UWTSD, DPA and GDPR policy in relation to security and retention of raw data and when this data can be destroyed. You should also be considering the policy of any external ethical organization (e.g. BPS).

22	List all who will have access to the data generated by the research activity:		
	(this box should expand as you type)		
23	List who will have control of, and act as custodian(s) for, data generated by the research activity:		
	(this box should expand as you type)		
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.		
	(this box should expand as you type)		
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)*		
	(this box should expand as you type)		
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

Remember to include the Date

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:**		**Date:**

For STUDENT Submissions:

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

For STAFF Submissions:

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

Include signature of your supervisor – do not forge this

GENERAL ISSUES REMEMBER . . .

Ensure that you Indicate either **'YES', 'NO'** or **N/A** For all that require a cross

YES	NO	N/A
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐

FINALLY . . .

This box is often marked in error

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.