

UNIVERSITY ETHICS COMMITTEE

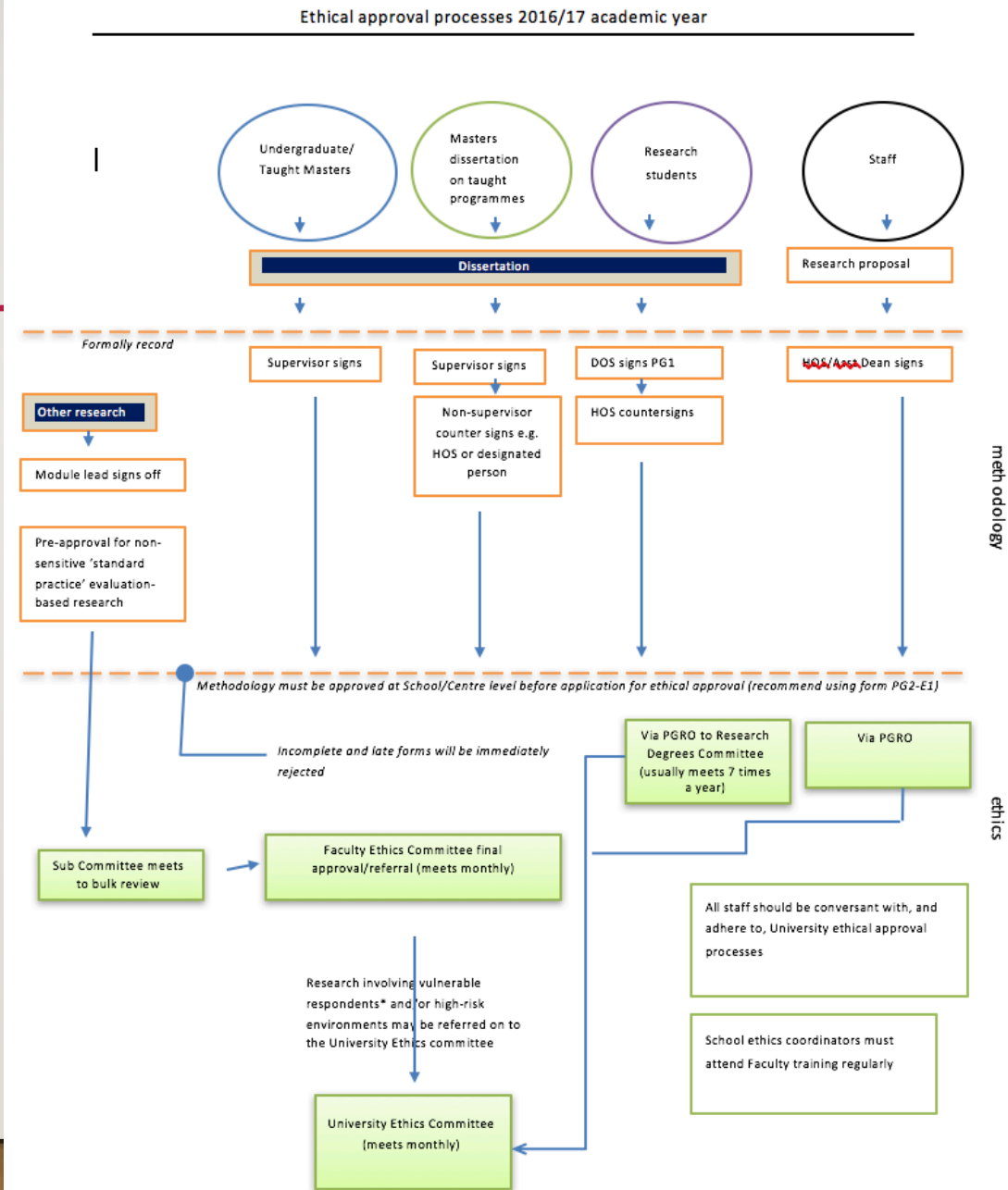
GUIDANCE ON SUBMITTING FORMS

SEPTEMBER 2019

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.
- There is an expectation that research design and methodology will have been approved for all research project proposals through School/Faculty processes **BEFORE** ethical approval is sought.
- Each academic discipline should establish a procedure to ensure the processes below are followed.
- All ethical approval applications are completed on the form **PG2-EI**.
 - Located in “complete list of forms” link on forms tab of the HWB.

THE PROCESS FOR SEEKING ETHICAL APPROVAL



10 COMMON SHORTCOMINGS

1. Section B:

- Omitting date

2. Section B:

- Omitting name of the staff member and their designated role

3. Section C:

- Omitting University Code of Ethics
- Not citing 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 K:

- Include signatures of supervisor
- These can be either electronic or handwritten

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
 - It is advisory to use bullet points for
 - Research Aims
 - Research Objectives
 - Research Questions
- Section G:
 - Ensure that you tick one the boxes either **'YES', 'NO'** or **N/A**

FURTHER GENERAL OBSERVATIONS

- Section H:
 - 'Adverse outcomes' should link to risks in preceding boxes
- Section I:
 - Make explicit reference to how 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. This does not mean saving work to a USB stick.
 - 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. Normally this would be the researcher and supervisor and in placement contexts, a leader or designated person.
 - Ensure that you provide details if boxes are ticked
- At the end of the form, do not include the Application Process or any appendices

SECTION B



PG2 / E1 FORM

SECTION B: Approval for Research Activity

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	
If Yes, please indicate source of approval (and date where known): <i>Approval in principle must be obtained from the relevant prior to seeking ethical</i>	Research Degrees Committee	☐		
	Faculty Research Committee	☐		
		☐		

Include Name of Staff
Member and their
Designated Role

Put in
Date

SECTION C

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, 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.

UWTSD Research Ethics & Integrity Code of Practice	☐
UWTSD Research Data Management Policy	☐
	☐

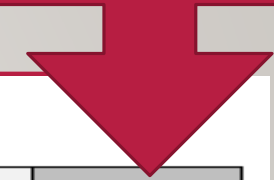
Now default to include UWTSD
Codes of Ethical Practice

Please note we would be FULLY
expecting you to also note appropriate
BPS guidance and cite this correctly.

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 organisations of the students', observational placements.

In these cases you would tick 'No'.



SECTION D: External Collaborative Research Activity

Does the research activity involve collaborators outside of the University?		YES	☐	NO	☐
If Yes, please provide the name of the external organisation and name and contact details for the main contact person and confirmation this person has consented to their personal data being shared as part of this collaboration.					
Institution					
Contact person name					
Contact person e-mail address					
Has this individual consented to sharing their details on this form?		YES	☐	NO	☐
Are you in receipt of a KESS scholarship?		YES	☐	NO	☐
Is your research externally funded		YES	☐	NO	☐
Are you specifically employed to undertake this research in either a paid or voluntary capacity?	Voluntary	YES	☐	NO	☐
	Employed	YES	☐	NO	☐
Is the research being undertaken within an existing UWTSD <u>Athrofa</u> Professional Learning Partnership (APLP)	If YES then the permission question below does not need to be answered.	YES	☐	NO	☐
Permission to undertake the research has been provided by the partner organisation	(If YES attach copy) If NO the application cannot continue	YES	☐	NO	☐

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



SECTION E (SLIDE 1)

SECTION E: Details of Research Activity

Indicative title:			
Proposed start date:		Proposed end date:	
Introduction to the Research (maximum 300 words) Ensure that you write for a <u>Non-Specialist Audience</u> when outlining your response to the three points below: • <i>Purpose of Research Activity</i> • <i>Proposed Research Question</i> • <i>Aims of Research Activity</i> • <i>Objectives of Research Activity</i> Demonstrate, briefly, how <u>Existing Research</u> has informed the proposed activity and explain • <i>What the research activity will add to the body of knowledge</i> • <i>How it addresses an area of importance.</i>			
Purpose of Research Activity (this box should expand as you type)		 Use research to provide background to the research area	
Research Question (this box should expand as you type)			
		 Research question and any hypotheses should be in this section	

SECTION E (SLIDE 2)

Aims of Research Activity (this box should expand as you type)	← Aims and Rationale in this box
Objectives of Research Activity (this box should expand as you type)	← Potential Research Implications here – and summarise the aims
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.	
 (this box should expand as you type)	← Important – this is the methods – design, materials and procedure should be here.

SECTION E (SLIDE 3)

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

(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.

(this box should expand as you type)

Use of documentation not in the public domain: Are any documents NOT publicly available?	NO	☐
	YES	☐

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 prevailing data protection law of the country in question and England and Wales.

(this box should expand as you type)

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

It will probably be N/A for this section

It will probably be no for this section

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
Use of a questionnaire or similar research instrument?	☐	☐
Use of interviews?	☐	☐
Use of diaries?	☐	☐
Participant observation with their knowledge?	☐	☐
Participant observation without their knowledge?	☐	☐
Use of video or audio recording?	☐	☐
Access to personal or confidential information without the participants' specific consent?	☐	☐
Administration of any questions, test stimuli, presentation that may be experienced as physically, mentally or emotionally harmful / offensive?	☐	☐
Performance of any acts which may cause embarrassment or affect self-esteem?	☐	☐
Investigation of participants involved in illegal activities?	☐	☐
Use of procedures that involve deception?	☐	☐
Administration of any substance, agent or placebo?	☐	☐
Working with live vertebrate animals?	☐	☐
Other primary data collection methods, please explain in this box For example, 'focus groups'. Please indicate the type of data collection method(s) in this box and tick the accompany box.	☐	☐
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 (SLIDE 1)

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SECTION G: Intended Participants			
Who are the intended participants:		YES	NO
Students or staff at the University?		☐	☐
Adults (over the age of 18 and competent to give consent)?			
Vulnerable adults?			
Children and Young People under the age of 8? (Consent from Parent, Carer or Guardian will be required)			
Prisoners?			
Young offenders?			
Those who could be considered to have a particularly dependent relationship with the investigator or a gatekeeper?			
People engaged in illegal activities?			
Others (please identify specifically any group who may be unable to give consent, please indicate here and tick the appropriate box.			
Other – please indicate here:			
(this box should expand as you type)			
Participant numbers and source Provide an estimate of the expected number of participants and how will they be recruited?		participants and	
How many participants are expected?	(this box should expand as you type)		
Who will the participants be?	(this box should expand as you type)		
How will you identify the participants?	(this box should expand as you type)		

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

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



Trinity Saint David

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

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



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

SECTION H

All research carries risk if it involves participants
ensure that risks are identified
Do not put '**Not applicable**'

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.

Full risk assessment completed and appended?	Yes	☐
	No	☐

Risks to participants

For example: emotional distress, financial disclosure, physical harm, transfer of personal data, sensitive organisational information

Risk to Participant: (this box should expand as you type)	How will you mitigate the Risk to Participant (this box should expand as you type)
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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)

Risks to investigator

For example: personal safety, physical harm, emotional distress, risk of accusation of harm/impropriety, conflict of interest

Risk to Investigator: (this box should expand as you type)	How will you mitigate the Risk to Investigator: (this box should expand as you type)
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University/institutional risks

For example: adverse publicity, financial loss, data protection

Risk to University: (this box should expand as you type)	How will you mitigate the Risk to University: (this box should expand as you type)
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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** informed consent, confidentiality and anonymity will be achieved

Make explicit reference to **HOW** informed consent, confidentiality and anonymity will be achieved

SECTION I: Feedback, Consent and Confidentiality

Feedback

What feedback will be provided to participants, how will this be done and when?

(this box should expand as you type)

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.

(this box should expand as you type)

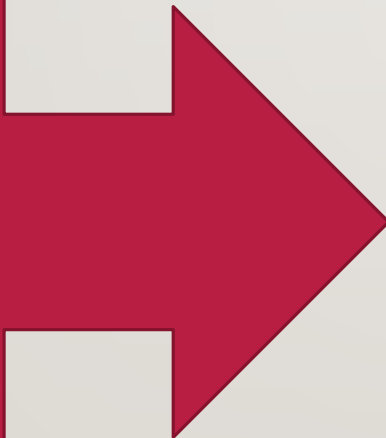
Confidentiality / Anonymity

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

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

In completing this section refer to the University's Research Data Management Policy and the extensive resources on the University's Research Data Management web pages (<http://uwtsd.ac.uk/library/research-data-management/>).

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
<i>"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.</i>	☐	☐

If YES, provide a description of the data and explain why this data needs to be collected:

(this box should expand as you type)

Does it involve special category data (as defined by the GDPR)?	YES	NO
<i>"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).</i>	☐	☐

If YES, provide a description of the special category data and explain why this data needs to be collected:

Please note this is for all stored data.

 (this box should expand as you type)		
Will the research activity involve storing personal data and/or special category data on one of the following:	YES	NO
Manual files (i.e. in paper form)?	☐	☐
University computers?	☐	☐
Private company computers?	☐	☐
Home or other personal computers?	☐	☐
Laptop computers/ CDs/ Portable disk-drives/ memory sticks?	☐	☐
"Cloud" storage or websites?	☐	☐
Other – specify:	☐	☐
For all stored data, explain the measures in place to ensure the security of the data collected, data confidentiality, including details of password protection, encryption, <u>anonymisation</u> and <u>pseudonymisation</u> :		
(this box should expand as you type)		

SECTION J (CONTINUED)

Electronic transfer of data means communicating data between electronic devices e.g. one database to another. This does **NOT** mean saving work to a USB stick



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All Data Storage		
Will the research activity involve any of the following activities:	YES	NO
Electronic transfer of data in any form?	☐	☐
Sharing of data with others at the University?	☐	☐
Sharing of data with other organisations?	☐	☐
Export of data outside the European Union or importing of data from outside the UK?	☐	☐
Use of personal addresses, postcodes, faxes, emails or telephone numbers?	☐	☐
Publication of data that might allow identification of individuals?	☐	☐
Use of data management system?	☐	☐
Data archiving?	☐	☐
If YES to any question, please provide full details, explaining how this will be conducted in accordance with the GDPR and DPA (and/or any international equivalent):		
<i>(this box should expand as you type)</i>		

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

Regarding storage of Raw data, make sure you are adhering the UWTSD, BPS, DPA and GDPR policy in relation to security and retention of raw data and when this data can be destroyed

List all who will have access to the data generated by the research activity:

(this box should expand as you type)

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)

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)

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)

Confirm that you have read the UWTSD guidance on data management (see <https://www.uwtsd.ac.uk/library/research-data-management/>)

YES ☐

NO ☐

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 ☐

NO ☐

SECTION K



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PG2 / E1 FORM

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](#)

Signature of applicant:		Date:
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Remember to
include the
Date

For STUDENT Submissions:

Director of Studies/Supervisor:	
Signature:	

Include signature of
your supervisor

These can electronic or handwritten – do not forge this

For STAFF Submissions:

Head of School/Assistant Dean:		Date:
Signature:		

GENERAL ISSUES

REMEMBER ...

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

[illegible]

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 (and have NOT completed Section H of this form) (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 Head of School.
☐	I have deleted the guidance notes before submitting the PG2 for consideration

REMEMBER!

delete the instructions
from the bottom of the form
before sending to your supervisor