

APPLICATION FOR ETHICAL APPROVAL

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 form must 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)

Full Name:	Maurice Cahill		
Tick all boxes which apply:			
Member of staff:	☐	Student:	☒
Honorary research fellow:	☐		
Faculty/School/Centre:	On Line and Distance Learning		
Campus:	N/A		
E-mail address:	emba@uwtsd.ac.uk		
Contact Telephone Number:	Dr Alex Bell		
For students:			
Student Number:	1504125	Undergraduate	☐
Programme of Study:	MBA	Taught Postgraduate	☒
Director of Studies/Supervisor:	Dr Roisin Mullins	Research	☐

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):	Research Degrees Committee	☐		
	Faculty Research Committee	☐		
	Other (write in)	☐		

Approval in principle **must** be obtained from the relevant source prior to seeking ethical approval.

SECTION C: 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.	
Whilst the author has been unable to locate any 'discipline specific codes of research', relating to the research at hand, the author shall adhere to the "major principles associated with ethical conduct" in qualitative research, identified by Mauthner et al (2002 p 54)	☒
	☐
	☐

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:				
Institution				
Contact person name				
Contact person e-mail address				

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

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				

SECTION E: Details of Research Activity

Indicative title:	Factors which influence the adoption of Operational Excellence in the Pharmaceutical industry		
Proposed start date:	September 2018	Proposed end date:	May 2019
Purpose of research activity (including aims and objectives) Outline the purpose, aims and objectives of the research activity, including key research questions. Show briefly how existing research has informed the proposed activity and explain what the research activity will add and how it addresses an area of importance. (Maximum 300 words)			
Title Factors which influence the adoption of Operational Excellence in the Pharmaceutical industry.			
Key Question To determine what is the nature of OE in the Pharmaceutical Industry and what influences its adoption.			
Objectives • Access the nature of Operational Excellence and specifically how it is positioned in the Pharmaceutical Industry • Explore, describe and categorise the factors that affect the adoption of Operational Excellence in the context of the Pharmaceutical industry. • Propose a conceptual framework to identify factors which may influence OE adoption in the pharmaceutical industry			

•Determine if there are similarities between factors identified in the conceptual framework and those described by experienced OE senior managers in the pharmaceutical industry.

(this box should expand as you type)

Proposed methods

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. (Maximum 600 words)

A qualitative methodology will be adopted to collate via semi structured interviews, the perceived challenges to adoption from expert and experienced Operational Excellence professionals.

Interviewing experienced Operational Excellence (OE) leaders from a number of pharmaceutical companies will provide a unique insight not currently available in the literature.

For the purposes of this research a group of five experts has been identified, this represents a number of OE senior managers from a selection of pharmaceutical companies in the UK and Ireland. The interviewees, companies and products shall be anonymised.

(this box should expand as you type)

Location of research activity

Identify all locations where research activity will take place.

The research will take place in the UK,

(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 sensitivities or vulnerabilities of participants.

N/A

(this box should expand as you type)

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	☐	☒

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

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 under 18?	☐	☒
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):	☐	☒

Participant numbers and source

Provide an estimate of the expected number of participants. How will you identify participants and how will they be recruited?

It is intended to interview 5 participants; these will be senior Operational Excellence managers in a number of pharmaceutical companies, the background and purpose of the research will be explained and the interviewees will be asked to participate by volunteering to be interviewed.

(this box should expand as you type)

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			
(this box should expand as you type)			

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			
(this box should expand as you type)			

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.
Risks to participants For example: emotional distress, financial disclosure, physical harm, transfer of personal data, sensitive organisational information
The participants will not experience any emotional distress during the interview process as it is essentially about their professional experiences leading and implementing Operational Excellence programs. The interviews will not encompass any financial disclosure, physical harm or transfer of personal data. No sensitive organisational information will be discussed,

(this box should expand as you type)
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
The research will not 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),
(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
Having considered the potential risks to the investigator identified above, the investigator deems that these are not applicable in this research.
(this box should expand as you type)
University/institutional risks For example: adverse publicity, financial loss, data protection
The author cannot identify any risks to the university. In terms of risk of not completing the research within the 2 years allowed from the start of this module, the author is confident of submitting the research within this time frame. This is based on a combination of past performance and identifying via a work breakdown structure the activities required to complete the research.
(this box should expand as you type)
Adverse outcomes List measures put in place to limit any adverse effects or outcomes of research activity where appropriate. Include any emergency protocols.
No adverse outcomes are anticipated
(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
Has a DBS certificate been obtained?	☐	☐	☒

SECTION I: Feedback, Consent and Confidentiality

Feedback What feedback will be provided to participants, how will this be done and when?
Feedback will be provided immediately after the interview, during the write up if required and again following completion, and marking of the research work
(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.

Each participant will be briefed regarding the background to the study, its purpose, and its potential benefits to the both the participants and the Operational Excellence community's body of knowledge. Consent shall also be reconfirmed at the commencement of each interview

(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.

The names of the participants, the companies they work for and any other company names or products inadvertently mentioned in the course of the interviews shall be anonymised.

(this box should expand as you type)

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/>).

	YES	NO
Does the research activity involve personal data (as defined by the Data Protection Act)?	☐	☒
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 sensitive personal data (as defined by the Data Protection Act)?	☐	☒
If YES, provide a description of the data and explain why this data needs to be collected:		
(this box should expand as you type)		

	YES	NO
Will the research activity involve any of the following activities:		
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 Data Protection Act (and/or any international equivalent):		
(this box should expand as you type)		

Will the research activity involve storing personal 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 data confidentiality, including details of password protection, encryption and anonymisation:		
N/A (this box should expand as you type)		
List all who will have access to the data generated by the research activity:		
Research supervisor (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:		
The University of Wales Trinity St David (this box should expand as you type)		
Give details of data storage arrangements, including where data will be stored, how long for, and in what form. Will data be archived – if so how and if not why not.		
Not applicable- (this box should expand as you type)		

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:

Tawne Cahn

Date:

14th Sept. 2018

For students:

Director of Studies/Supervisor:	<i>Dr Roisin Mullins</i>
Signature:	
Date:	

For staff:

Head of School/Assistant Dean:	
Signature:	
Date:	

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 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.

RESEARCH STUDENTS AND 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. You will be informed of the outcome of your claim by email; therefore it is important that you check your University and personal email accounts regularly.

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.

This form is available electronically from the Academic Office web pages:

<http://www.uwtsd.ac.uk/academic-office/>