

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 or following 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 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)

1	Full Name:	Kayleigh Phillips			
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:	Institute of Education and Humanities: Psychology and Counselling			
4	Campus:	IQ Campus, SA1, Swansea			
5	E-mail address:	2012754@student.uwtsd.ac.uk			
6	Contact Telephone Number:	07881767474			

For students:		
7	Student Number:	2012754
8	Programme of Study:	BSc Psychology and Counselling
9	Director of Studies/Supervisor:	Dr Ceri Phelps

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	☐		
		Institute Research Committee	☐		
		Other (write in) Dr Ceri Phelps/Dr Zoe Cooke	☒	05.08.2024	

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	UWTSD Student Code of Conduct ☒
4	UWTSD Data Protection and Storage Protocol ☒
5	BPS Code of Ethics and Conduct (2021) ☒
6	BPS Ethics Guidelines for Internet-Mediated Research (2021) ☒
7	BPS Data Protection Regulation: Guidance for Researchers (2018) ☒

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	☒
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:	A comparison of unmet support needs and quality of life in females pre and post endometriosis diagnosis in Wales: an online survey.			
2	Proposed start date:	31/10/2024	Proposed end date:	01/07/2025	
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: <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 Existing Research 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>					
3	Purpose of Research Activity The purpose of this research activity is to understand the psychosocial impact of waiting for a diagnosis of endometriosis for females in Wales by comparing quality of life and unmet support needs amongst those waiting for a diagnosis and those already diagnosed. Endometriosis is a health condition that impacts 1 in 10 individuals, with waiting times for diagnostic laparoscopy estimated to be around 8-10 years (Endometriosis UK, 2024), in Wales this is 9 years. Symptoms include chronic pelvic pain, dysmenorrhea, pain during and after sexual intercourse, fatigue, nausea, problems with fertility, depression or anxiety, among more (World Health Organisation, 2023). There is a vast amount of research into the impact of waiting for medical diagnosis on psychological wellbeing, such as depression and anxiety, in conditions such as organ				

transplant and cancer treatment (Gagliardi et al., 2021), fertility and IVF treatment (Bolvin & Lancaster, 2010) as well as common gynaecological and urogynaecological conditions (Royal College of Obstetricians and Gynaecologists, 2022). However, little investigation has been conducted surrounding those awaiting formal diagnosis for endometriosis for either investigative laparoscopy or for those diagnosed for excision.

Quality of life (QoL) is defined by the National Library of Medicine as a concept which captures the wellbeing, both positively and negatively, of an individual's existence at a specific point in time. The Endometriosis Health Profile (EHP-30) is a health-related quality of life (QoL) scale, specifically anchored towards endometriosis (Jones et al., 2001). The EHP-30 successfully addresses concerns felt by individuals with endometriosis when clinically compared to general QoL scales to identify the impact of surgical and medical interventions (Jones et al., 2024). This study will implement the EHP-30 core scale, in addition to the optional 23 questions from the 6 supplementary modules, to assess QoL for those awaiting a diagnosis and with a formal diagnosis to gather quantitative data.

Further additional exploration will be implemented through additional questions designed to explore the current support and information needs, as well as education of participants and wellbeing techniques for symptom management, to potentially establish effective support interventions for those awaiting formal diagnosis, such as those identified in endometriosis research, such as that of As-Sanie et al. (2019).

Reference List

As-Sanie, S., Black, R., Giudice, L. C., Gray Valbrun, T., Gupta, J., Jones, B., Laufer, M. R., Milspaw, A. T., Missmer, S. A., Norman, A., Taylor, R. N., Wallace, K., Williams, Z., Yong, P. J., & Nebel, R. A. (2019). Assessing research gaps and unmet needs in endometriosis. *American Journal of Obstetrics and Gynecology*, 221(2), 86–94. 10.1016/j.ajog.2019.02.033

Bolvin, J., & Lancaster, D. (2010). Medical waiting periods: Imminence, emotions and coping. *Women's Health*, 6(1), 59–69. <https://doi.org/10.2217/whe.09.79>

Endometriosis UK. (2024). *"Dismissed, ignored and belittled" The long road to endometriosis diagnosis in the UK*. Retrieved from <https://www.endometriosis-uk.org/sites/default/files/2024-03/Endometriosis%20UK%20diagnosis%20survey%202023%20report%20March.pdf>.

Gagliardi, A. R., Yip, C. Y., Irish, J., Wright, F. C., Rubin, B., Ross, H., Green, R., Abbey, S., McAndrews, M. P., & Stewart, D. E. (2021). The psychological burden of waiting for procedures and patient-centred strategies that could support the mental health of wait-listed patients and caregivers during the COVID-19 pandemic: A scoping review. *Health Expectations*, 24(3), 978–990. <https://doi.org/10.1111/hex.13241>

Jones, G. L., Budds, K., Taylor, F., Musson, D., Raymer, J., Churchman, D., Kennedy, S. H., & Jenkinson, C. (2024). A systematic review to determine use of the endometriosis health profiles to measure quality of life outcomes in women with

	endometriosis. <i>Human Reproduction Update</i>, 30(2), 186–214. https://doi.org/10.1093/humupd/dmad029 Jones, G., Jenkinson, C., Wong, J., Barnard, A., & Kennedy, S. (2001). Development of an endometriosis quality-of-life instrument: The endometriosis health profile-30. <i>Obstetrics & Gynecology</i>, 98(2), 258–264. https://doi.org/10.1016/s0029-7844(01)01433-8 Royal College of Obstetricians and Gynaecologists (2022, April 6) <i>Left for too long: Understanding the scale and impact of gynaecology waiting lists</i>. Available at: https://rcog.shorthandstories.com/lefttoolong/?_gl=1*hzkj8o*_ga*MTIxNzI1MzY1NC4xNzMwMzg3ODIz*_ga_JH4R6DLLJJ*MTczMDM4NzkwNC4xLjAuMTczMDM4NzkwMC4wLjAuMA..#group-section-Foreword-LiwE2VBZtN World Health Organization (2023, March 23) <i>Endometriosis</i>. Available at: https://www.who.int/news-room/fact-sheets/detail/endometriosis (this box should expand as you type)
4	Research Question How do quality of life and psychosocial support needs of females waiting for formal diagnosis of endometriosis in Wales compare to that of females already diagnosed? (this box should expand as you type)
5	Aims of Research Activity 1. To understand the psychological impact of diagnostic waiting times for endometriosis in Wales compared to those already with a diagnosis 2. To identify current unmet information and support needs in those waiting for a diagnosis compared to those already with a diagnosis. 3. To identify current wellbeing techniques and support in those waiting for a diagnosis and those already with a diagnosis. (this box should expand as you type)
6	Objectives of Research Activity 1. To compare self-reported quality of life between those with and without a formal diagnosis in Wales. 2. To explore and compare current preferences for support needs, based on multiple choice questions and free-text qualitative data. 3. To identify any unmet information and support needs in individual's waiting for formal diagnosis 4. To investigate current wellbeing techniques utilised by those with and without a formal diagnosis in Wales

5. To investigate current information and education provided in individuals waiting for a formal diagnosis and identify potential gaps within this.
6. To analyse the above information to make recommendations for future education, psychological intervention and support within future research.

(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.

An anonymous online cross-sectional survey, utilising the online survey tool Qualtrics, will be used to capture data from females over the age of 18 that are pre or post endometriosis diagnosis within Wales. Basic demographic information, such as age, self-identified gender and ethnicity, will be collected as well as whether participants have a self-diagnosis/awaiting a diagnosis or whether they have a medical diagnosis of endometriosis to place them into two groups. Next, participants will begin the two-part study.

During the first part of the study, participants will take part in the study accessed through a QR code or direct link. Participants will then view an information sheet, providing a study brief. After obtaining consent, participants will be required to state whether they have a self-diagnosis/awaiting a diagnosis or whether they have a medical diagnosis of endometriosis to place them into two groups. Next, they will be asked to complete the unmet needs survey followed by the EHP-30 core scale, in addition to the optional 23 questions from the 6 supplementary modules, based on symptoms and QoL within the last 4 weeks.

For the second element, participants will complete additional questions designed to explore the current support and information needs, as well as education of participants and wellbeing techniques for symptom management. These will be displayed as multiple-choice questions, with a free text option to add any additional information participants deem relevant. An example of these questions include "Have you conducted independent research on endometriosis, or similar conditions, from any other avenue?" with multiple-choice options such as social media or charity organisations, as well as a free text option for others.

Participants will be presented with an online debrief form upon completion and thanked for their participation.

Unmet needs Unmet needs are defined in the literature as difficulties receiving a service in response to a problem that significantly interferes with daily life (Alonso et al. 2007) or as the "invisible factors" that may significantly affect health and well-being but that often go undetected and unattended by the formal healthcare system (Van de Port et al., 2007). In this survey participants will firstly be asked to indicate if they feel they have had any unmet needs in relation to their endometriosis in the last month. If they indicate no, then the participants will be directed to the next set of questions measuring quality of life. If participants indicate that they have had unmet needs, then they will be directed to further questions asking participants to indicate from a list of potential unmet needs which ones have applied to them. They will also be asked to indicate in a first free text box which has been their biggest priority/unmet need over the last month with the opportunity to

	expand/explain if they wish to. Data from the unmet needs survey will allow us to identify the main areas of unmet need within females in Wales awaiting formal diagnosis compared to those with a formal diagnosis. Quality of Life: The Endometriosis Health Profile (EHP-30) is a 30-item health-related QoL scale developed by Jones et al. (2001) specifically developed to assess health related QoL in endometriosis. Split within 5 scale scores, the EHP-30 covers how often these areas of concern are experienced by an individual over the last 4 weeks of symptoms to provide an overview of a complete menstrual cycle. These scale scores include pain, control and powerlessness, social support, emotional wellbeing and self-image The EHP-30 successfully addresses concerns felt by individuals with endometriosis when clinically compared to general QoL scales to identify the impact of surgical and medical interventions (Jones et al., 2024; Khong et al., 2010). Examples throughout each of the scale scores include <i>Felt your appearance has been affected?</i>; <i>Felt unable to forget your symptoms?</i> and <i>Been unable to sleep properly because of the pain?</i>. Participants are asked to rate on a 5-point Likert scale how much they agree with each statement. Analysis: For the QoL questions, participant scores for each sub-scale will be calculated, divided by the maximum score and multiplied by 100. Once scores are calculated for each sub-scale, these will then be totalled for an overall QoL score. Each scale is rated between 0 – 100, with 0 being the best health score and 100 being the worst health score. Scores on the domains will be compared between the pre and post diagnosis groups using unrelated t-tests. Unmet need will be compared between those pre and post diagnosis by comparing frequencies of responses to each category of unmet need using chi-square analysis and appropriate descriptive statistics. Responses to free text data will be explored using thematic analysis (Braun & Clarke, 2006), which is a technique used to analyse patterns in qualitative research in order to uncover themes, will be used to interpret responses and frequency from multiple choice responses will be calculated. (this box should expand as you type)
	Location of research activity Identify all locations where research activity will take place.
8	All active research activity will be taking place online, due to the nature of the participant pool it is imperative to have easy access to the questionnaire and research. (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	N/A

	(this box should expand as you type)
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10	Use of documentation not in the public domain: Are any documents <u>NOT</u> 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:		
	Proposed research is directly in line with the Well-being of Future Generations (Wales) Act 2025's 3rd wellbeing goal and measure of a healthier Wales. This goal describes ensuring both physical and mental health are the best that they can be as well as understanding that the choices we make affect health in the future. By assessing the psychosocial impact of those both pre and post endometriosis diagnosis, this research will highlight both physical and mental challenges faced by this population. There is also the potential for the improvement of the 4th wellbeing goal, a more equal Wales. Although endometriosis can be a chronic condition, there is no recognition of this being a disability at present. During the All-Party Parliamentary Group on Endometriosis (2020), a common theme reported and identified was that assessors and health care professionals during applications for different disability related benefits did not understand the condition or that the condition can fluctuate and is reoccurring. (this box should expand as you type)		

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?	Target number of participants for this study will be 40 in each group, although additional responses would be preferred. Consideration has been taken from Jones et al. (2004), whereby only 40 of the participants selected responded to the surveys. (this box should expand as you type)
11	Who will the participants be?	Participants will be individuals assigned female at birth (AFAB) over the age of 18 that are currently undergoing investigation for endometriosis, have a self-diagnosis and those who have a medically confirmed endometriosis diagnosis as the two participant groups. (this box should expand as you type)
12	How will you identify the participants?	Participants will be recruited via opportunity/convenience sampling, through online social media platforms, forum sites, UWTSD EMS as well as approaching social support groups within Wales. This will be presented in the form of an initial study advert (to be approved by supervisor) directing participants to an online information sheet outlining a summary of the aims and objectives of the study, as well as providing a QR code or link to access the survey. (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			
	Online consent will be obtained through ticking a box on Qualtrics in lieu of a signed consent form. This is considered acceptable practice for online studies in accordance with BPS Guidelines for Internet-mediated Research (2021). <i>(this box should expand as you type)</i>			

	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			
	<i>(this box should expand as you type)</i>			

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: 1. Participants may feel there is a risk of being identified as health data is being disclosed.	How you will mitigate the risk to participants: 1. One of the main ethical considerations within this research is that of anonymity. As discussing sensitive topic areas, namely an individual's medical diagnosis, experience and unmet needs, emphasis will need to be made on the anonymisation of data. This is paramount due to any fear of sharing or impacting participants healthcare. It will be made clear in the information sheet, consent form and the debrief that participation in this study will not impact an individual's	

	2. There may be a risk to participants regarding the sensitive nature of topics by disclosing medical information, both physical and psychological. 3. Participants may have concerns regarding the safety and storage of data collected within this research. <i>(this box should expand as you type)</i>	healthcare, nor will it be traceable. Demographic information taken will remain basic, to further ensure responses will not have any implication on medical treatment or be tied to any medical information. A study ID number will be used for qualitative responses, and gender-neutral pronouns will be used, such as in Windrim, McGuire and Durand (2024). Qualitative responses will remain limited regarding free text options, and participants will not be requested to share any personal information/experiences they do not wish to disclose. 2. To reduce the potential for harm, both the information sheet and consent form will be presented to prospective participants before completing the study. This will allow for clarity on the nature of what will be discussed. Upon completion of the study, participants will also be presented with a debrief form that will reiterate the participants right to withdraw, should they no longer wish to participate due to any distress caused. 3. For mitigation, the researcher will disclose within the information sheet and debrief sheet how data will be stored after collection. Anonymity and confidentiality will be made clear to participants, as well as providing contact information if there are any further questions about the storage and safety of the data. The option to remove data from the study will be made clear and participants will be made aware of this option prior to data completion. After completion and submission, data will be anonymised, and removal may not be possible. <i>(this box should expand as you type)</i>
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	
	Information outlining any potential risks meeting this criterion are outlined above. At the end of the study, there will be resources provided, such as Endometriosis UK online support chat and telephone number, so that if participants have experienced any distress whilst completing and were still happy to share their data, they can access help and support through professional channels. <i>(this box should expand as you type)</i>	
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: 1. Participants will all receive the email of the researcher to answer any further questions they may have. With this access, it opens the possibility for the researcher to receive negative emails from participants pertaining to the research. 2. There is the potential for the researcher to be accused of harm, distress or improper behaviour should the situation arise that a participant feels they are unhappy with the study. This is particularly relevant due to the nature of participants being asked to disclose physical and mental health information during participation.	How you will mitigate the risk to the investigator: 1. To mitigate the level of contact between researcher and participant(s), participants taking part in the study will only be provided with the researcher's UWTSD email address. This will allow for no personal contact information to be shared with others. Should a situation arise where negative emails are received, the researcher will inform the dissertation supervisor when this occurs. Both the researcher and participants will be expected to conform with UWTSD Student Code of Conduct to ensure professional responses and behaviour from all parties involved. 2. For mitigation, the researcher will adhere to the BPS Code of Human Research Ethics (2021), the BPS Ethics Guidelines for Internet Mediated Research (2021), as well as UWTSD Research Ethics & Integrity Code of Practice. This will ensure that the researcher is acting with integrity and maintaining a professional working relationship with participants and ensuring their rights are upheld. All participants will receive an information sheet outlining the nature and aims of the research to allow for an informed decision to be made on whether they would be happy to take part. A consent form will be provided also, as well as a debrief form with the reminder of the right to withdraw before submitting any responses.

	3. There is the potential for information outside of the students' knowledge as an undergraduate student that they may be asked. <i>(this box should expand as you type)</i>	3. For mitigation, should this situation arise, the researcher will signpost and direct to the dissertation supervisor where appropriate. <i>(this box should expand as you type)</i>
5	University/institutional risks For example: adverse publicity, financial loss, data protection	
	Risk to the University: 1. As this is an undergraduate empirical project, there is the potential risk to the reputation of UWTSD. This would occur in the instance the researcher and/or participants do not abide by protocols and ethical procedures in place. If a participant does not fully understand the nature of the study regarding the disclosure of physical and mental health information. 2. There is the potential for data produced during this research to be leaked, exposed and used in ways that were unintended by the study. <i>(this box should expand as you type)</i>	How you will mitigate the risk to the University: 1. To mitigate, the researcher will abide by the BPS Code of Ethics and Conduct (2021) and as well as UWTSD Code of Conduct throughout the study. Participants will also receive the opportunity to contact both the researcher and supervisor should they have any questions pertaining to the study before providing final consent for data to be used. The researcher will maintain professional conduct throughout the process. 2. To mitigate this, all data collected and stored will be in accordance with UWTSD's Research Data Management Policy. The data will only be used as outlined for the purpose of this study, to remain compliant with BPS Code of Human Research Ethics (2021), BPS Ethics Guidelines for Internet-Mediated Research (2021) and UWTSD Research Ethics & Integrity Code of Practice. All data collected and stored will be anonymised and held within a password protected file. Only the researcher, supervisor and if requested external examination board will only have access to the data collected at any point during research to reduce this risk. Data will also be treated in accordance with General Data Protection Regulation (2016) and the Data Protection Act (2018). <i>(this box should expand as you type)</i>
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:

	1. As research is internet-mediated, there is a limited risk to the environment. However, there is the potential for the researcher to require the printing resources required during thematic analysis. <i>(this box should expand as you type)</i>	1. To minimise this, the researcher will endeavour to make use exclusively of digital methods. If the researcher requires to print any additional information to conduct this study, any materials used will be shredded to maintain security and recycled in line with Welsh Government Policies. <i>(this box should expand as you type)</i>
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	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.			

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?
	All participants upon completion of the questionnaire section of the study will receive a debrief form outlining the aims and objectives of the study. Participants will again be reminded of their right to withdraw from the study. At this point, participants will also have the opportunity to engage with the researcher and ask any additional questions they may have. Upon completion of the second part of the study, participants will receive a debrief form, detailing the reasons for the additional information and how the responses from these questions will be analysed (thematic analysis) to inform and suggest support and education within the healthcare system regarding individuals' pre-diagnosis of endometriosis. All debriefing methods will follow the BPS and UWTSD Guidelines. <i>(this box should expand as you type)</i>
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.
	Prior to data collection, an information sheet detailing the general aims and objectives of the study will be presented. Once the participant has had some time to read through this, they will be presented with a consent form outlining their rights as a participant such as the right to withdraw at any time. For those engaging in the second part of the study, a separate information sheet will be presented. Once this has been read, participants will be introduced with a consent form that highlights their rights as a participant. <i>(this box should expand as you type)</i>
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.
	One of the main ethical considerations will be that of anonymity. As discussing sensitive topic areas, namely an individual's medical history and experience emphasis will need to be made on the anonymisation of data. This is paramount due to any fear of sharing or impacting participants healthcare. It will be made clear in the information sheet, consent form and the debrief that participation in this study will not impact an individual's healthcare, nor will it be traceable. Demographic information taken will remain basic, to further ensure responses will not have any implication on medical treatment or be tied to any medical information. To assure further anonymity, pseudonyms will be given to report qualitative responses in the second part of the study, and gender-neutral pronouns will be used, such as in Windrim, McGuire and Durand (2024). <i>(this box should expand as you type)</i>

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 study will collect demographic data, such as the participants age and preferred gender to produce descriptive statistics for this study. As well as this, individual's medical information and experience will also be collected to complete the Endometriosis Health Profile 30 (EHP-30; Jones et al., 2001). To interpret and identify themes through thematic analysis of the qualitative responses obtained, further information will be required about the participant's physical and mental health experiences regarding endometriosis and the diagnostic processes to assess the psychosocial impact of waiting times within the NHS and potentially establish effective support interventions during this time. <i>(this box should expand as you type)</i>		
	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	Individual's medical information and experience will also be collected and disclosed to complete the EHP-30 (Jones et al., 2001). To interpret and identify themes through thematic analysis of the qualitative responses obtained, further information will be required		

	about the participant's physical and mental health experiences regarding endometriosis and the diagnostic processes to assess the psychosocial impact of waiting times within the NHS and potentially establish effective support interventions during this time. <i>(this box should expand as you type)</i>
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	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 study will collect data in regard to participants mental and physical health and wellbeing as part of the measures and questionnaires used in order to gather the data needed. Upon completion, this data will be scored and averaged. Any additional answers for those pre-diagnosis will go through thematic analysis in order to interpret and gather themes. <i>(this box should expand as you type)</i>		

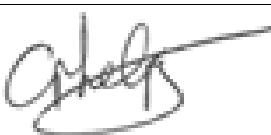
Data Protection			
		YES	NO
	Will the research activity involve any of the following activities:		
13	Electronic transfer of data in any form?	☒	☐
14	Sharing of data with others at the University outside of the immediate research team?	☐	☒
15	Sharing of data with other organisations?	☐	☒
16	Export of 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 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): Data will be required to be shared between the researcher and the dissertation supervisor. This will be shared via a secure Microsoft OneDrive.		

	All data storage regarding this research will adhere with UWTSD Data Collection Policy and the BPS Data Protection Regulation: Guidance for Researchers (2018). <i>(this box should expand as you type)</i>		
22	List all who will have access to the data generated by the research activity:		
	Kayleigh Phillips (researcher) and Dr Ceri Phelps (dissertation supervisor) will have access to this data. If requested, an examination board may also need to access the data obtained. <i>(this box should expand as you type)</i>		
23	List who will have control of, and act as custodian(s) for, data generated by the research activity:		
	Kayleigh Phillips (researcher) and Dr Ceri Phelps (dissertation supervisor). <i>(this box should expand as you type)</i>		
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.		
	All data will be stored within the researcher's password protected account within UWTSD's Qualtrics system. Data stored within Qualtrics will all be anonymised to protect the participant's identity. If downloaded, all data will be protected and stored on the researcher's private laptop, which is password protected. Any files holding this data will be anonymous and password protected also. Once the external examiners have reviewed the Empirical Project, all data will be deleted unless stored in the university repository for the purposes of publication All data storage regarding this research will adhere with UWTSD Data Collection Policy and the BPS Data Protection Regulation: Guidance for Researchers (2018). <i>(this box should expand as you type)</i>		
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. <i>(Most relevant to academic staff)</i>		
	Yes – there may be the possibility of publication. <i>(this box should expand as you type)</i>		
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:	Kayleigh Phillips	Date: 04.11.24

For STUDENT Submissions:

2	Director of Studies/Supervisor:	Dr Ceri Phelps	Date: 04.11.24
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 College Portal** 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.

Appendices

Appendix A – Study Information Sheet

Study Information Sheet

A comparison of unmet support needs and quality of life in females pre and post endometriosis diagnosis in Wales: an online survey

This document provides key information regarding the study and provides details about what will be expected of you as a participant. Therefore, please read this information carefully before providing consent to take part.

The purpose of this study is to compare the Quality of Life (QoL) and unmet needs of those pre and post endometriosis diagnosis living in Wales. As well as this, this study hopes to identify wellbeing techniques currently utilized by those pre and post diagnosis and to assess informational and educational needs.

The aims of this study are:

- To understand the psychological impact of diagnostic waiting times for endometriosis within Wales compared to those already with a diagnosis
- To identify current unmet information and support needs in those waiting for a diagnosis compared to those already with a diagnosis.
- To identify current wellbeing techniques and support in those waiting for a diagnosis and those already with a diagnosis.

During this study you will be required to do the following:

- Fill out an online demographic questionnaire asking you for basic demographic information, as well as the status of your endometriosis diagnostic journey.
- Any needs you may have experienced throughout your diagnostic journey that you did not receive any help and/or support for within the last four weeks (one menstrual cycle).
- Completion of the Endometriosis Health Profile in order to create a QoL score based on the last 4 weeks (one menstrual cycle).

At the end of the study, you will be provided with the study debrief.

If you have any questions or concerns about this study, please contact the researcher (Kayleigh Phillips, 2012754@student.uwtsd.ac.uk) or the dissertation supervisor (Dr Ceri Phelps, ceri.phelps@uwtsd.ac.uk).

If you are happy to take part in this study, please click the button below to direct you to the consent form for the study.

If you feel you want to leave the study, you can do so at any time by closing the browser on your computer or notifying the researcher. Once the study has ended you will be asked if you want your data to be saved as part of the study. If you agree, then your data will be anonymised and therefore untraceable to later delete. If you do not wish for your data to be used, please ensure you inform the researcher.

Appendix B – Consent Form



Study Consent Form

I understand that this research study is being carried out by a 3rd year Psychology and Counselling Student for the purpose of their undergraduate dissertation research, and that taking part in this study will involve completing a questionnaire assessing health related quality of life in those pre/self-diagnosis or those who have received a formal medical diagnosis of endometriosis.

I understand that this study will take approximately 30 minutes to complete.

I understand that participation in this study is voluntary, and I am free to withdraw participation at any time during or before the end of the study without giving a reason.

I understand that once I complete the study my data will remain confidential and will not be traced back to me as a code will be assigned in place of my name and unique identification number. The data collected will be stored indefinitely in accordance with the Data Protection Act.

I am aware that if I have concerns about the study, I can contact the researcher, Kayleigh Phillips, at any time during or after the study on 2012754@student.uwtsd.ac.uk or Empirical Project Supervisor, Dr Ceri Phelps, on ceri.phelps@uwtsd.ac.uk, should I have any concerns.

I also understand that at the end of the study I will be provided with a debrief form.

Please tick the boxes below to confirm:

“ I am aged 18 years of age or over

“ I understand I can withdraw at any time without penalty

“ I understand my data will be held confidentially with a code assigned in place of my name

“ I understand all the above information on this consent form

“ I understand prior study restrictions and requirements before completing this consent form

“ I consent to taking part in this study

Appendix C – Debrief Sheet



Centre for Psychology and Counselling
SA1 Campus
Swansea

Study Debrief Sheet

A comparison of unmet support needs and quality of life in females pre and post endometriosis diagnosis in Wales: an online survey

Thank you for taking part in this study.

The aim of this study was to explore whether unmet support needs and quality of life differs between those pre and post endometriosis diagnosis within Wales. We specifically wanted to explore whether individuals with a self-diagnosis/pre diagnosis had lower quality of life scores compared to those with a formal medical diagnosis of endometriosis. As well as this, this study aims to identify educational, informational and support needs in order to best inform future research and identify unmet needs currently not considered within practice.

Previous literature has suggested waiting periods can have an impact on our psychosocial wellbeing within other conditions (Gagliardi et al., 2021; Bolvin & Lancaster, 2010). Currently, there is no genetic biomarkers for endometriosis which are non-invasive, as accurate diagnosis requires surgery it contributes to the growing waiting times for diagnosis (Horne & Saunders, 2019).

Research has also suggested a multidisciplinary approach when it comes to endometriosis care to best implement long-term treatment plans and provide emotional support (Fang et al., 2023). However, according to NICE Guidelines (2017) for endometriosis identifies the gap in research regarding information and support interventions to best meet need to improve health related quality of life and daily executive functions.

Should you feel you require additional support regarding endometriosis, you can contact Endometriosis UK via 0808 808 2227, or enquire about local support groups and online support at: <https://www.endometriosis-uk.org/get-support>

If you wish to withdraw your data from the study, you must tell the researcher now. After this point, all of your data will remain confidential, and we will not trace it back to you.

If taking part in this study has raised any questions, please speak to the researcher, Kayleigh Phillips (2012754@student.uwtsd.ac.uk) or contact dissertation supervisor: Dr Ceri Phelps (ceri.phelps@uwtsd.ac.uk)

Thank you once again for taking time to participate in this study.

BSc Psychology and Counselling

University of Wales Trinity Saint David, Swansea

Appendix D – Endometriosis Health Profile 30

The EHP-30 CORE questionnaire:

Pain

- P1 Been unable to go to social events because of the pain?
- P2 Been unable to do jobs around the home because of the pain?
- P3 Found it difficult to stand because of the pain?
- P4 Found it difficult to sit because of the pain?
- P5 Found it difficult to walk because of the pain?
- P6 Found it difficult to exercise or do the leisure activities you would like to do because of the pain?
- P7 Lost your appetite and/or been unable to eat because of the pain?
- P8 Been unable to sleep properly because of the pain?
- P9 Had to go to bed/lie down because of the pain?
- P10 Been unable to do the things you want to do because of the pain?
- P11 Felt unable to cope with the pain?

Control & Powerlessness

- C&P12 Generally felt unwell?
- C&P13 Felt frustrated because your symptoms are not getting better?
- C&P14 Felt frustrated because you are not able to control your symptoms?
- C&P15 Felt unable to forget your symptoms?
- C&P16 Felt as though your symptoms are ruling your life?
- C&P17 Felt your symptoms are taking away your life?

Emotional Wellbeing

- EW18 Felt depressed?
- EW19 Felt weepy/tearful?
- EW20 Felt miserable?
- EW21 Had mood swings?
- EW22 Felt bad tempered or short tempered?
- EW23 Felt violent or aggressive?

Social Support

- SS24 Felt unable to tell people how you feel?
- SS25 Felt others do not understand what you are going through?
- SS26 Felt as though others think you are moaning?
- SS27 Felt alone?

Self Image

- SI28 Felt frustrated as you cannot always wear the clothes you would choose?
- SI29 Felt your appearance has been affected?
- SI30 Lacked confidence?

The EHP-30 Modular questions:

Work

- W1 Had to take time off work because of the pain?
- W2 Been unable to carry out duties at work because of the pain?
- W3 Felt embarrassed about symptoms at work?
- W4 Felt guilty about taking time off work?
- W5 Felt worried about not being able to do your job?

Children

- C1 Found it difficult to look after your child/children?
- C2 Been unable to play with your child/children?

Sexual intercourse

- SI1 Experienced pain during or after intercourse?
- SI2 Felt worried about having intercourse because of the pain?
- SI3 Avoided intercourse because of the pain?
- SI4 Felt guilty about not wanting to have intercourse?
- SI5 Felt frustrated because you cannot enjoy intercourse?

Medical profession

- MP1 Felt the doctor(s) you have seen is (are) not doing anything for you
- MP2 Felt the doctor(s) think it is all in your mind?
- MP3 Felt frustrated at the doctor(s) lack of knowledge about endometriosis?
- MP4 Felt like you are wasting doctor(s) time?

Treatment

- T1 Felt frustrated because treatment is not working?
- T2 Found it difficult coping with the side effects of treatment?
- T3 Felt annoyed at the amount of treatment you have had to have?

Fertility

- F1 Felt worries about the possibility of not having children/more children?
- F2 Felt inadequate because you may not/have not been able to have children/more children?
- F3 Felt depressed at the possibility of not having children/more children?
- F4 Felt that the possibility of not conceiving/ not being able to conceive has put a strain on your personal relationship?