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| Application for  Research Governance & Ethics  Approval | Cais i Gymeradwyo Llywodraethiant a Moeseg Ymchwil |

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| * ALL applicants are asked to complete Section 1. * ALL academic staff & postgraduate research (PhD/Prof Doc/MPhil) students should complete the first two sections of this form. * Postgraduate Taught (MSc) students should complete ALL sections of this form. * If academic staff or PGR students require School Research Ethics approval, please also complete Section 3. * Students should not submit their proposals for review until seen and approved by their supervisor/s. * Please note that word limits, which vary for different categories of applicant, are the *maximum* allowed. * Please ensure all accompanying documentation is attached as separate appendices, **not in PDF format.** * Completed applications should be sent to: [HCAREEthics@cardiff.ac.uk](mailto:HCAREEthics@cardiff.ac.uk) as a WORD document. |

**SECTION 1: *to be completed by all applicants***

1. **Project Title** (*This should accurately reflect the content and scope of the proposed study)*

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1. **Name of Lead Applicant**

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1. **Application Details**

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| **Is this project: (please tick where appropriate)** | |
| 1. Led by someone in their capacity as an HCARE staff member? |  |
| 1. Led by someone in their capacity as an HCARE postgraduate research student? (PhD, M Phil, Prof Doc) |  |
| 1. Led by someone in their capacity as an HCARE postgraduate taught student? (MSc) |  |
| 1. led by someone outside of HCARE, includes HCARE staff members as part of the research team |  |
| 1. Planning to access HCARE students and/or Staff for the purposes of data generation? |  |
| 1. A manuscript produced by a member, or members, of HCARE staff which it is planned will be published as an internal document? |  |

1. **Personal Details**

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| Name of Lead Investigator |  | |
| Contact address |  | |
| Email |  | |
| Telephone |  | |
| Name/s of co-applicants  (if any) |  | |
| Name of grant awarding body (if any) |  | |
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| **FOR HCARE STAFF APPLICANTS:**  **(Excludes staff registered for a higher degree)**  Has your line manager agreed in principle that this project can proceed? | | **YES/NO** |
| Name of line manager |  | |
| If you wish, you may suggest the name of a member of HCARE staff who you feel has the capacity/expertise to review the application. This person must not have had any prior input into the application. |  | |
| **FOR STUDENT APPLICANTS (including staff registered for Higher Degrees):** | | |
| Level & Programme of study (e.g., PhD, MSc Healthcare, MSc Gynae) |  | |
| Name of supervisor(s) |  | |
| Name of clinical supervisor (if applicable) |  | |
| Supervisor’s email |  | |
| Is this submission linked to any other studies being undertaken within the School  e.g. other studies, lead investigators etc  If Yes, please give details | | **YES/NO** |

1. **Project participants; highlight as appropriate**

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| Will your study involve NHS staff? | | **YES/NO** |
| Will your study involve Cardiff University staff as participants? | | **YES/NO** |
| Will your study involve Cardiff University students as participants? | | **YES/NO** |
| Will your study involve anyone with learning difficulties? | | **YES/NO** |
| \*Will your study involve vulnerable adults? | | **YES/NO** |
| \*Will your study involve Children (under 16 years of age)? | | **YES/NO** |
| Will your study involve Patients? (NHS (HRA) Approval is required) | | **YES/NO** |
| Will your study involve people in custody? | | **YES/NO** |
| Will your study involve people engaged in illegal activities? | | **YES/NO** |
| \*Will your study involve any other vulnerable group not listed here? | | **YES/NO** |
| ***\*If yes****,* please indicate whether, or not, you have read and understood the University’s Safeguarding Children and Vulnerable Adults Policy, a copy of which can be found at:  <https://intranet.cardiff.ac.uk/staff/research-support/integrity-and-governance/research-ethics> | Yes –  I have read and understand the Policy  No -  I have not read or understood the Policy | |
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**Recruitment Procedures**

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| **i.** | *If necessary,* do you have an up-to-date Disclosure and Barring Service (DBS) check?  *(DBS checks have replaced Criminal Record Bureau (CRB) checks)* | **YES** | **NO** |
| **ii.** | Does your project include people who are, or are likely to become, your students/clients or students/clients of the place in which you work? |  |  |
| **iii.** | Does your project require information/data from people for whom English/ Welsh is not their first language? |  |  |
| **Iv** | Does your study require a research passport or letter of access? |  |  |

1. **Research Governance, Health, Safety & Risk**

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| 1. *All applicants are expected to comply with the principles of research governance as set out by Cardiff University.*   Research Governance can be defined as the broad range of regulations, principles and standards of good practice that exist to ensure the highest standards of quality research. This covers scientific quality, ethical standards and all aspects of research management. Please indicate whether, or not, you have read and understood the University’s Research Integrity & Governance Code of Practice, a copy of which can be found at:  <http://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/good-practice-and-quality>   1. *All applicants must provide evidence that a risk assessment has been undertaken.*   Applicants are reminded of the importance of taking health and safety issues into account when designing their proposals, and of ensuring that their plans are in accordance with Cardiff University and School policies and requirements in this area. Specifically, you should consider any specific risks (a) to the Researcher (e.g. if it is planned that the research be conducted off site, and/or where the project involves a lone fieldworker), and (b) to the Research Participant/s (e.g. using equipment, physical/mental interventions which may cause harm).  Cardiff University policy on health and safety can be downloaded from: <http://www.cardiff.ac.uk/osheu/index.html>.  *If applicable,* have you taken into account Cardiff University guidance on health and safety, including undertaking risk assessments, guidance for lone workers? | Yes –  I have read and understand the Policy  No -  I have not read or understood the Policy  **YES/NO** |

1. **Signature**

In signing this form the applicant confirms that the relevant academic, professional, health and safety measures and University Policy and School requirements have been taken into account for the proposed research and that appropriate approval has been obtained.

**Applicant:**

**Name:**

**Signature: Date:**

**SECTION 2: *to be completed by all applicants (unless submitting project plans using templates specified by external organisations e.g., grant awarding bodies)***

1. **Project Summary (Staff and PGR applicants: 400 words max; PGT applicants: 300 words max)**

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| *Provide an abstract which briefly in* ***LAY*** *terms, states the following:*   * *the problem/gap in current knowledge* * *rationale* * *study aim* * *study design* * *participants* * *study outcomes and impact* |

1. **Background (Staff and PGR applicants: 1000 words max; PGT applicants: 300 words max)**

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| *Give an overview of the literature which summarises and appraises previous research in the field.*  *Conclude with rationale for proposed study based on ‘gaps’ in understanding or challenges to current practices.* |

1. **Purpose of the study (staff and PGR applicants: 300 words max; PGT applicants: 200 words max)**

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| *What is the research question? It is important that the focus of the study has been ‘problematised’.*  *Identify sub-questions and study aims and objectives as appropriate.* |

1. **Methodological/theoretical concepts/frameworks (staff and PGR applicants: 800 words max. 500 words for PGT applicants)**

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| *Give an overview of the approach used, (qualitative, quantitative or mixed methods) to explore the research question and explain how it will inform your study.* |

1. **Research Methods (Staff and PGR applicants: 800 words max; PGT applicants: 500 words max)**

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| *Summarise the methods you intend to use; setting and recruitment; data collection tools. State how data will be managed, i.e. statistical tests/coding of qualitative texts; use of software applications such as SPSS or NVivo.* |

1. **Research Governance Approvals & Ethical Considerations**

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| *Summary of the approvals process to be followed (NHS/School Research Ethics Committee; NHS R&D approval; University Sponsorship; HRA; other permissions* | |
| Will your study require NHS Research & Development Review (R&D)?  *If yes,* which Local/University Health Board/NHS Trusts will be required to give approval? | **YES/NO** |
| Will your study require NHS (HRA) Ethical Review? | **YES/NO** |
| Will your study require Cardiff University to act as Sponsor under the NHS Research Governance and Insurance requirements? | **YES/NO** |
| Will your study require review by another body e.g. schools, prisons, etc.  *If yes,* please give further information | **YES/NO** |
| Will your study require review by another body outside the UK? If Yes, please give details | **YES/NO** |

1. **Location of Study and Access arrangements**

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| *Please give details on where study is to be sited and access negotiations/arrangements* | |
| Has informal consent been obtained to access these facilities/participants?  *(Evidence of consent NOT required if using HCARE internal facilities)*  If YES, please provide documentary evidence, if NO, why not? | **YES/NO** |
| Please provide details of the designated contact in the host country who will provide assurance related to the conduct of the study and support for you during the data collection period: |  |

1. **Timetable**

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| *Identify a realistic, up to date timeline of key milestones over the course of the study, this can be done in the form of a Gant chart as an appendix* |

1. **References**

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| *Use Harvard style.* |

1. **List of Appendices which have been attached separately with this form**

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| *e.g. Participant information sheets, data collection protocols, consent forms, completed health and safety checks, risk assessment forms, etc. Please number and label clearly. This should* ***not*** *be a PDF* |

**SECTION 3: To be completed by all applicants seeking School ethical approval**

**(Please tick as appropriate)**

1. **Consent Procedures**

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|  | | **YES** | **NO** |
| **i.** | Will you tell participants that their participation is voluntary? |  |  |
| **ii.** | Will you obtain:   1. written consent for participation in studies excluding questionnaires? 2. implied consent where questionnaires are utilised? |  |  |
| **iii.** | If the research is observational, will you ask participants for their consent to being observed? |  |  |
| **iv.** | If you are proposing to audio/video record participants, will you ask for their consent for this to take place? |  |  |
| **v.** | If you are proposing to include direct quotations from participants in any study dissemination/write-up etc., will you ask for their consent to include these? |  |  |
| **vi.** | Will you tell participants that they may withdraw from the research at any time, and without the need to give reasons for withdrawal? |  |  |
| **vii.** | Will you tell participants that they may withdraw from the research at any time, and may withdraw their data? |  |  |
| **viii.** | Will you give potential participants over 24 hours to consider participation? |  |  |
|  | **If NO to any of above, please give reasons** |  |  |

1. **Possible Harm to Participants**

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|  | | **YES** | **NO** |
| **i.** | Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? |  |  |
| **ii.** | Is there any realistic risk of any participants experiencing a detriment to their interests as a result of participation? |  |  |
|  | If yes, provide details |  |  |

1. **Data Protection**

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|  | | **YES** | **NO** |
| **i.** | (a) Will any non-anonymised and/or personalised data be generated?  (b) and/or stored? |  |  |
| **ii.** | Will you have access to documents containing sensitive data about living individuals?  Sensitive data are *inter alia* data that relates to racial or ethnic origin, political opinions, religious beliefs, trade union membership, physical or mental health, sexual life, actual and alleged offences. |  |  |
| *If “Yes”* will you gain the consent of the individuals concerned to access this? |  |  |

1. **Records Management**

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|  | | **YES** | **NO** |
| **i.** | Will you be following Cardiff University guidance on data management and storage? If no, why not?  <http://www.cardiff.ac.uk/govrn/cocom/recordsmanagement/recordsretention/recordreten.html> |  |  |

1. **Additional Research Governance Issues**

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|  | | **YES** | **NO** |
| **i.** | Are there any additional research governance issues arising in the context of this study (for example, does the study involve: use of a drug, unusual randomisation or blinding?)  If your study include the use of a drug, you will need to contact Research Governance before submission ([resgov@cf.ac.u](mailto:resgov@cf.ac.u)k) |  |  |
| **ii.** | Does the study have implications for Data Protection?  If YES, please give details: | **YES** | **NO** |
| **iii.** | Have you undertaken a risk assessment (appropriate to the level of possible harm)?  If YES, please attached evidence of outcome with application  If NO, why not? | **YES** | **NO** |

1. **Human Tissue**

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|  | | **YES** | **NO** |
| **i.** | Does the study involve the collection or use of human tissue (including, but not limited to, blood, saliva and bodily waste fluids)?  *If yes,* a copy of the submitted application form and any supporting documentation must be emailed to the Human Tissue Act Compliance Team (HTA@cf.ac.uk). A decision will only be made once these documents have been received. |  |  |

1. **Presentation**

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|  | | **YES** | **NO** |
| **i.** | Have you included relevant version numbers and dates in the running footers contained in your proposal, information sheet/s and consent form/s? |  |  |

1. **Details of Ethical Considerations (500 words max)**

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| **If you identified any possible ethical issues above, please give question number/subsection and state how these will be managed.** **Or**  **If there are any other potential ethical issues that you think the Committee should consider please explain below. It is your obligation to bring to the attention of the Committee any ethical issues not covered on this form.** |