|  |
| --- |
| Application for Project  and/or  School Research Ethics  Approval |
| Please indicate to which committee/s you are applying:   |  |  | | --- | --- | | Research Review & Ethics Screening (SREC) for   * PhD and Professional Doctorate (DAHP) students going on to apply for NHS ethics approval who need review for Cardiff University Sponsorship. |  | | School Research Ethics Committee (SREC) for:   * Postgraduate Taught Students Research Ethics Review * Postgraduate Research Students Research Ethics Review * Members of academic staff preparing submissions to external organisations |  | |
|  |

|  |
| --- |
| * ALL applicants are asked to complete Section 1. * Members of academic staff preparing submissions to external organisations (e.g., grant awarding bodies) should feel free to submit their proposals for scientific review using the forms provided/specified by the external organisation, rather than completing Section 2. * Postgraduate Research (MPhil/Doctoral) students should complete the first two sections of this form. * If academic staff or PGR students require School Research Ethics approval, please also complete Section 3. * Postgraduate Taught (MSc.) students should complete ALL sections of this form. * 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. * Completed applications should be sent to: HCAREethics@cardiff.ac.uk * **Applications for scientific review prior to submission to grant awarding bodies should be clearly identified as such and flagged as ‘high priority’.** |

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

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

|  |
| --- |
|  |

1. **Name of Lead Applicant**

|  |
| --- |
|  |

1. **Application Details**

|  |  |
| --- | --- |
| **Is this project (*please answer all questions*):** | |
| 1. Led by someone in their capacity as an HCARE staff member? | YES/NO |
| 1. Led by someone in their capacity as an HCARE postgraduate research student? | YES/NO |
| 1. Led by someone in their capacity as an HCARE postgraduate taught student? | YES/NO |
| 1. (a) led by someone in their capacity as an HCARE staff member or student and (b) is being prepared for submission to a grant awarding body? | YES/NO |
| 1. (a) led by someone outside of HCARE (b) includes HCARE staff members as part of the research team and (c) is being prepared for submission to a grant awarding body? | YES/NO |
| 1. (a) led by a member of staff or student in HCARE (b) has already been scientifically reviewed and is being supported and (c) is now being submitted for HCARE REC approval? | YES/NO |
| 1. Planning to access HCARE students for the purposes of data generation? | YES/NO |
| 1. A manuscript produced by a member, or members, of HCARE staff which it is planned will be published as an internal document? | YES/NO |
| 1. Please indicate if you wish any correspondence to be available through the medium of Welsh | YES/NO |

1. **Personal Details**

|  |  |  |
| --- | --- | --- |
| Name of Lead Investigator |  | |
| Contact address |  | |
| Email |  | |
| Telephone |  | |
| Names of co-applicants (if any) |  | |
| Name of grant awarding body (if any) |  | |
| **FOR HCARE STAFF APPLICANTS:**  Has your line manager agreed in principle that this project can proceed? | | YES/NO |
| Name of line manager |  | |
| Manager’s address |  | |
| Manager’s email |  | |
| Manager’s telephone |  | |
| *If application is being prepared for submission to an external grant awarding body*: has your intention to apply for funding been approved following completion of a Research Proposal Notification form? | | YES/NO |
| **FOR STUDENT APPLICANTS:** | | |
| Programme of study (e.g., PhD, MSc) |  | |
| Name of supervisor(s) |  | |
| Supervisor’s email |  | |
| Supervisor’s telephone number |  | |
| Is this submission for review being made with the express support of your supervisor(s)? | | YES/NO |

1. **To be completed by HCARE staff: congruence with HCARE strategy and plans to maximise impact**

|  |
| --- |
| 1. Projects proposed by members of staff in HCARE are linked to the School Research Strategy, or are developed with reference to other strategic interests of the School and its partner NHS organisations. **Please explain how this project *either* fits with the School Research Strategy, *or* otherwise advances the School’s strategic interests**. 2. In the Research Excellence Framework 2014 document, *Assessment framework and guidance on submissions* [<http://www.hefce.ac.uk/research/ref/pubs/2011/02_11/>], research impact is defined as ‘an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia’. **Please describe how you have considered ‘impact’ in your project plans**. 3. 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. |

1. **Project Participants**

|  |  |  |
| --- | --- | --- |
| Will your study involve NHS patients, carers or their families? | | YES/NO |
| 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 anybody under the age of 16? | | 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:  [http://www.cardiff.ac.uk/racdv/ethics/guidelines/FINAL Safeguarding Children & VAs Policy 2010.doc](http://www.cardiff.ac.uk/racdv/ethics/guidelines/FINAL%20Safeguarding%20Children%20&%20VAs%20Policy%202010.doc) | Yes –  I have read and understand the Policy  No -  I have not read or understood the Policy | |
| 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/NO |
| Will your study involve anyone with ‘Limited Capacity’? | | YES/NO |
| Where appropriate, have you the applicant given due regard to the ‘Prevent duty’, in particular, to prevent anyone being drawn into terrorism?  <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445916/Prevent_Duty_Guidance_For_Higher_Education__England__Wales_.pdf>  <http://www.cardiff.ac.uk/public-information/policies-and-procedures/freedom-of-speech> | | YES/NO/  Not applicable |

1. **Signatures**

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.

**Applicant:**

**Name: Date:**

**Signature:**

**Student (Academic) Supervisor:**

**Name: Date:**

**Signature:**

**Student (Clinical) Supervisor: (where applicable)**

**Name: Date:**

**Signature:**

***HCARE Staff Applicants only***

**Line Manager**

**Name: Date:**

**Signature:**

**SECTION 2: *to be completed by applicants who are not submitting their 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)**

|  |
| --- |
| *Provide an abstract which briefly 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)**

|  |
| --- |
| *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)**

|  |
| --- |
| *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 Framework (staff and PGR applicants: 800 words max; NOT REQUIRED for PGT applicants)**

|  |
| --- |
| *Give an overview of the approach used to explore the research question and explain how it will inform your study.* |

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

|  |
| --- |
| *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**

|  |  |
| --- | --- |
| *Summary of the approvals process to be followed (NHS/School Research Ethics Committee; NHS R&D approval; University Sponsorship; other permissions* | |
| Will your study require NHS Research & Development Review (R&D)?  *If yes,* which Local Health Board/Trusts will be required to give approval? | YES/NO |
| Will your study require NHS 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 School of Healthcare Sciences Ethical Review? | YES/NO |
| Will your study require review by another body e.g. schools, prisons, etc.  *If yes,* please give further information. | YES/NO |

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

|  |  |
| --- | --- |
| *Please give details below on where study is to be sited and access negotiations/arrangements both within HCARE and externally:* | |
| Has informal consent been obtained to access external facilities/participants?  *Please provide email or letter of confirmation as an attachment* | YES/NO |
| Has informal consent been obtained to access the HCARE Research Centre for Clinical Kinaesiology facilities Contact details: VandeursenR@cardiff.ac.uk  *Please provide email or letter of confirmation as an attachment* | YES/NO |
| Has informal consent been obtained to access the HCARE Simulation Suite/ equipment? Contact details: HCARESimulation@cardiff.ac.uk  *Please provide email or letter of confirmation as an attachment* | YES/NO |
| Has informal consent been obtained from the simulation team to access the equipment required for this study? This would include items such as emg, video cameras and portable forceplate  Contact details: HCARESimulation@cardiff.ac.uk  *Please provide email or letter of confirmation as an attachment* | YES/NO |

1. **Dissemination and promotion of impact (staff and PGR applicants: 300 words max; NOT REQUIRED for PGT applicants)**

|  |
| --- |
| *Identify study outcomes and strategies for ensuring your findings will inform practice/policy.* |

1. **Timetable**

|  |
| --- |
| *Identify a realistic timeline of key milestones over the course of the study.* |

1. **References**

|  |
| --- |
| *Use Harvard style.* |

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

|  |
| --- |
| *e.g. Participant information sheets, data collection protocols, consent forms, completed health and safety checks, risk assessment forms, etc. Please number and label clearly.* |

**SECTION 3: *to be completed by applicants requiring School of Healthcare Sciences Research Ethics Approval only (i.e. Excludes NHS Health Research Authority (HRA) approvals)***

**Before completing this section, researchers are strongly advised to read the School’s *Research Ethics Guidance* document, available at: http://www.cardiff.ac.uk/HCARE ethicsguidance**

*Use the following questions to identify any possible ethical issues as these relate both to researchers and participants.* ***You only need to tick the box if your answer is YES/NO as appropriate. Where this occurs give further details/information as required in Box 10.***

1. **Project summary (300 words max)**

|  |
| --- |
| *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. **Recruitment Procedures**

|  |  |  |
| --- | --- | --- |
|  | | **Yes** |
| **i.** | Does your project include people with learning or communication difficulties? |  |
| **ii.** | Does your project include people in custody? |  |
| **iii.** | Is your project likely to include people involved in illegal activities? |  |
| **iv.** | Does your project include generating data about the practice of health and/or social care staff? |  |
| **v.** | Does your project involve people belonging to a vulnerable group, other than those listed above? |  |
| **vi.** | *If necessary,* do you have an up-to-date Disclosure and Barring Service (DBS) check?  *(DBS checks have replaced Criminal Record Bureau (CRB) checks)* |  |
| **vii.** | 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? |  |
| **viii.** | Does your project require information/data from people for whom English / Welsh is not their first language? |  |

1. **Consent Procedures**

|  |  |  |
| --- | --- | --- |
|  | | **No** |
| **i.** | Will you tell participants that their participation is voluntary? |  |
| **ii.** | Will you obtain:  a. written consent for participation in studies excluding questionnaires *or*  b. 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 give potential participants a significant period of time to consider participation? |  |

1. **Possible Harm to Participants**

|  |  |  |
| --- | --- | --- |
|  | | **Yes** |
| **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? |  |

1. **Data Protection**

|  |  |  |
| --- | --- | --- |
|  | | **Yes** |
| **i.** | Will any non-anonymised and/or personalised data be generated and/or stored? |  |
| **ii.** | Will you have access to documents containing sensitive[[1]](#footnote-1) data about living individuals? |  |
| *If “Yes”* will you gain the consent of the individuals concerned to access this? |  |

1. **Records Management**

|  |  |  |
| --- | --- | --- |
|  | | **No** |
| **i.** | Will you be following Cardiff University guidance on data management and storage? |  |

1. **Additional Research Governance Issues**

|  |  |  |
| --- | --- | --- |
|  | | **Yes** |
| **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?) |  |
| **ii.** | Does the study have implications for Data Protection? |  |

1. **Human Tissue**

|  |  |  |
| --- | --- | --- |
|  | | **Yes** |
| **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**

|  |  |  |
| --- | --- | --- |
|  | | **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)**

|  |
| --- |
| **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.** |

1. 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. [↑](#footnote-ref-1)