**School of Healthcare Sciences**

**Research Ethics Committee**

**Lead Reviewer’s Comments Form**

The Committee seeks to provide a transparent and robust approach to the ethical scrutiny of research conducted by students and staff of the School and grant ethical approval where deemed appropriate. Ethical review also includes an element of scientific review, as supporting poor science would be unethical. The Lead Reviewer process adopted will **guide** the Committee to approve, require amendments and to issue guidance on research where the responsibility to conduct an ethics review does not fall to a REC within the NHS, proposals involving human research participants, human material or human data.

Thank you for agreeing to review we would welcome your comments in these specific areas to help guide our decision-making.

The lead reviewer(s) should complete this form in preparation for the School Research Ethics Committee meeting. Completed forms should be emailed to [HCAREthics@cardiff.ac.uk](mailto:HCAREthics@cardiff.ac.uk). This form is the basis for feedback to applicants and will be sent to them.

The form has specific tick boxes, if an area needs more work/clarification. The space below each section allows for more detailed feedback. Clearly label which section comments refer to ie 1B then identifying any further information required

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| Name of Applicant: | |
| Status: Staff/Student | Name of Supervisor (where applicable): |
| Discussed with Supervisor: YES/NO | Has the supervisor been copied in: YES/NO |
| Meeting Date: | Review Return Date: |
| Name of reviewer: | |
| Study Title: | |

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| 1. **Social or scientific value; scientific design and conduct of the study** | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Is there a clear aim and focus for the study |  |  |  |  |
| 1. Literature support: Is the research question important and necessary? |  |  |  |  |
| 1. Is there evidence present in the proposal to justify the study? |  |  |  |  |
| 1. Is there evidence of the use of accepted scientific principles and methods to produce reliable and valid data? |  |  |  |  |
| 1. Is the research design appropriate to the proposed study and research question? |  |  |  |  |
| 1. Is the proposed data analysis able to answer the research question? |  |  |  |  |
| 1. Is there involvement of patients, service users, and the public in the design, management, and undertaking the research? (N/A for MSc) |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |
| 1. **Recruitment arrangements and access to health information and participant selection** | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Does the proposal provide evidence of appropriate inclusion and exclusion of potential research participants? |  |  |  |  |
| 1. Is it clear how research participants are recruited? |  |  |  |  |
| 1. Will NHS staff be recruited? \*If Yes, Will need NHS R&D approval\* |  |  |  |  |
| 1. Will NHS patients be recruited? \* If Yes, Will need HRA approval\* |  |  |  |  |
| 1. Is it clear how participation impacts on their clinical care? |  |  |  |  |
| 1. Is it clear how participation impacts on the participants if healthy volunteers/students? |  |  |  |  |
| 1. Are compensation arrangements in place? Insurance (any risk of harm). |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| 1. **Are the anticipated benefits/risks for research participants (present and future) identified?** | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Is there evidence of a risk assessment being undertaken supporting minimisation of risks? |  |  |  |  |
| 1. Is there evidence of the consideration of any benefits/risk for individual research participants? |  |  |  |  |
| 1. Are risks clearly identified for the research participant? |  |  |  |  |
| 1. Have steps been taken to minimise discomfort and distress (Physical or Other)? |  |  |  |  |
| 1. Have the potential benefits been described? |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |
| 1. **Care and protection of research participants; respect for potential and enrolled research participants’ welfare and dignity.** | | | | |
| Does the proposal and accompanying participant information sheet(s) and consent form(s) consider: | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Permitting withdrawal from the research? |  |  |  |  |
| 1. Protecting privacy through confidentiality? |  |  |  |  |
| 1. Informing participants of newly discovered risks or benefits? (N/A for BSc/MSc students) |  |  |  |  |
| 1. Informing participants of results of research? |  |  |  |  |
| 1. Maintaining welfare of participants? |  |  |  |  |
| 1. \*\*What will happen to the participants at the end of the study? E.g. back to usual care |  |  |  |  |
| 1. The provision of appropriate indemnity? |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| Has the proposal outlined data protection and research participant’s confidentiality? | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Has the proposal outlined data protection and research participant’s confidentiality? |  |  |  |  |
| 1. Where and how (anonymised/coded) and for how long will data be stored? |  |  |  |  |
| 1. What purpose will be served by the data? |  |  |  |  |
| 1. Who will have access to the data? |  |  |  |  |
| 1. Are research participants informed that access to their medical notes may be required? |  |  |  |  |
| 1. Have arrangements been made to deal with incidental disclosure? |  |  |  |  |
| 1. Has Cardiff University guidance been acknowledged? |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| 1. **Have the informed consent processes and research participant information requirements been outlined?** [Provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate.] | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Is the language used clear and understandable to the research participant it is aimed at? |  |  |  |  |
| 1. Does it include all the procedures as described in the proposal? |  |  |  |  |
| 1. Has any uncertainty and randomisation been explained to the research participant? |  |  |  |  |
| 1. Is consent taken as part of a process with research participants having adequate time to consider the information, and opportunity to ask questions? |  |  |  |  |
| 1. Is it clear to what the research participant consents or assents? |  |  |  |  |
| 1. Is there any inducement or coercion? |  |  |  |  |
| 1. Are vulnerable research participants involved? |  |  |  |  |
| 1. Has a letter of access been obtained from the research venue if applicable? |  |  |  |  |

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|  | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Has language and culture been acknowledged? |  |  |  |  |
| 1. Have translation issues been considered? |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| 1. **Is the research team suitably qualified?** [Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications] | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Are applicant and supporting staff suitably qualified and do they have experience relevant to the proposed research? (N/A for student applications) |  |  |  |  |
| 1. Is this research on patients or healthy volunteers requiring the supervision of a competent and appropriately qualified physician or other health care professional? |  |  |  |  |
| 1. Are the local facilities and arrangements suitable? |  |  |  |  |
| 1. Have community issues such as facilities, access or privacy been considered? |  |  |  |  |
| 1. Have any conflicts of interest been considered? |  |  |  |  |
| 1. [For students] Is this proposal unique to this individual or is there collaboration with others? |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| 1. **Is appropriate supporting information provided? If required:** | **YES** | **NO** | **N/A** | **Unclear** |
| 1. Is an interview schedule available? |  |  |  |  |
| 1. Is a draft questionnaire provided? |  |  |  |  |
| 1. Have the risks of lone working been acknowledged? |  |  |  |  |
| 1. Have appropriate letters of access been provided (eg for access to equipment) |  |  |  |  |
| Reviewer’s comments/issues for discussion | | | | |

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| **OUTCOME** | (Please tick) |
| A favourable ethical opinion |  |
| A favourable ethical opinion subject to conditions |  |
| A provisional opinion subject to the committee receiving further information |  |
| An unfavourable opinion |  |