**JRMO SOP 14**

**Associated Document 4**

**Review Form**

***This form provides an optional template for Review Committees to record the various aspects of review of clinical research. It may be useful for the investigator to complete some of the details in advance; these sections are shaded.***

***Please read the SOP 14 Review of Research, the Guidance document (AD1), and other Associated Documents for guidance in advance of completing this form.***

FORM STRUCTURE

Section A: Study identifiers and basic information

Section B:

* Funding
* Protocol Review
* Confirmation of Scientific Peer Review
* Reputational Risk
* Conflicts of Interest
* *AUTHORISATION*

Section C:

* Capacity & Capability
* *AUTHORISATION*

***Section A: STUDY IDENTIFIERS AND BASIC INFORMATION***

*Guidance note: It may be useful if the researcher completes the information in Section A and the further shaded sections in B1.*

|  |  |
| --- | --- |
| Study Title |  |
| IRAS Number |  |
| Chief Investigator (CI) |  |
| Chief Investigator’s Department  (Queen Mary Institute and Barts Health department/ Clinical Board) |  |
| Sponsor Organisation | Barts Health or Queen Mary  *(please delete as appropriate* |

***Section B: DEPARTMENTAL REVIEW***

|  |  |
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| ***Section B1: FUNDING***  *Refer to grant application details on Worktribe system, funding section of JRMO Research Protocol and IRAS application form.* | |
| If a grant application was submitted, were the appropriate departmental authorisations given at grant application stage? | Y / N  Give details: |
| Is this a commercial or non-commercial study? | Commercial / non-commercial  *(please delete as appropriate)* |
| Are all the research costs sufficiently covered by funds available? | Y / N  Give details: |
| Are there any Excess Treatment Costs? | Y / N  If yes, please specify |
| If above information entered by researcher, does the Review Committee confirm the above details are accurate? | Y / N |
| Does the CI’s department agree to underwrite any shortfall or unexpected overspend? |  |

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| ***Section B2: PROTOCOL REVIEW***  *Ensure sight of the latest version of the Research Protocol.* | | |
| Does the protocol give a clear description of the practical way in which the study will be conducted? |  |

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| --- | --- |
| ***Section B3: CONFIRMATION OF SCIENTIFIC PEER REVIEW***  *This section constitutes confirmation of the suitability of the chosen scientific peer reviewers, as opposed to a record of the scientific peer review itself. The Review Committee should refer to JRMO SOP14 and AD1 Review of Research Guidance for Barts Health and Queen Mary criteria on independence of scientific peer reviewers.* | |
| Status of the scientific peer review. It has been:  *(please delete as appropriate)* | Submitted and in progress  Completed  Not submitted |
| How many scientific peer reviewers have been invited to undertake peer review? |  |
| Are the identified scientific peer reviewers suitable and qualified to review this research study? |  |
| If applicable, have the reviewers’ comments been accepted and incorporated into the revised version of the Protocol? |  |
| If not, and the original Protocol remains unchanged further to reviewers’ comments, has justification been provided? |  |

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| ***Section B4: REPUTATIONAL RISK***  *Reviewer to assess the potential reputational risk to the sponsor organisation, and if appropriate the proposed research sites, with regard to:*   1. *highly sensitive, controversial or security-sensitive topics* 2. *CI and study team experience and expertise (specifically in relation to organisational risk, as opposed to appropriateness of team to deliver the study)* 3. *the likelihood of successful delivery and completion, considering previous audits if applicable* 4. *performance of CI and study team, including registration and reporting of previous studies* 5. *potential conflicts of interest and mitigations* | |
| Based on the above, does the reviewer believe that this study, led and managed by Queen Mary and/or Barts Health, represents a higher than acceptable reputational risk to the institution(s)? | Comments: |

|  |  |
| --- | --- |
| ***Section B5: CONFLICTS OF INTEREST***  *Refer to sections the CI has declared potential conflicts of interests in: the JRMO Protocol and IRAS application form* | |
| In the opinion of the reviewer, do any of the CI’s declared interests represent a conflict? |  |
| Does the reviewer themselves declare a potential conflict of interest, with regard relationship with the CI/study team or financial gain from the study? |  |

***Authorisation for the review aspects listed in Section B.* *To be signed by Review Committee Chair/Clinical Director or Institute Director***

***NAME:***

***ROLE:***

***DEPARTMENT:***

***SECTION C: CAPACITY & CAPABILITY***

*Refer to the JRMO list of authorised persons for who can approve a research site C&C.*

*This section is relevant for:*

*- sponsored studies where Barts Health/Queen Mary is also a research site in the study. It is possible the reviewer who authorises Section B also authorises Section C, but only in the case where the CI’s department is also the proposed research site.*

*- hosted studies that are taking place at Barts Health/Queen Mary but are not sponsored by Barts Health/Queen Mary (these studies need to complete Section C only).*

*[Sponsored studies not taking place at Barts Health/Queen Mary need not complete Section C: they will need C&C at the local research site(s) instead.]*

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| --- | --- |
| Is the study team appropriate to lead/run this study? |  |
| Is the study team adequately resourced? |  |
| Does the Principal Investigator (PI) have sufficient time to lead this project (consider work plan and existing commitments)? |  |
| Does the team have capacity to run this project (staff and facilities)? |  |
| Are there existing studies that would act as competing for the same participant cohort? |  |
| Is the funding appropriate and sufficient? |  |
| Is the research site CB / Institute willing to underwrite any costs? |  |
| Does the study fit with the CB / Institute research strategy? |  |
| Can this research project be successfully delivered (recruiting to target and Protocol compliance) at this site? |  |
| Based on the above, does the reviewer believe that this study, to be conducted at Queen Mary and/or Barts Health, represents a higher than acceptable reputational risk to the institution(s)? |  |

***Authorisation for the Capacity & Capability review aspects listed in Section C.***

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| Does the C&C reviewer themselves declare a potential conflict of interest, with regard relationship with the CI/study team or financial gain from the study? |  |

***NAME:***

***ROLE:***

***DEPARTMENT:***