**Sponsorship Review Checklist and Summary**

**Study Title:**

**CI:**

**Funder:**

***Summary of proposed research***

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| 1. **Administrative details**
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|  | **Delete as appropriate** | **Comment (if required)** |
| Is the Chief Investigator (CI) employed by the Trust? | Yes/No |  |
| Is this a multi-centre study? | Yes/No |  |
| Is the final protocol available? | Yes/No |  |
| Has a peer review been provided? | Yes/No |  |
| Has evidence of funding been provided? Please check as N/A if no funding required | Yes/No |  |
| For interventional studies has PPI involvement reviewed occurred? | Yes/No |  |
| Are all documents clearly identified with version numbers, dates and IRAS number? | Yes/No |  |
| Are the titles consistent throughout the documents (either long or short titles used as appropriate)? | Yes/No |  |
| Dates of study Start date: End of study: |  |  |
| Number of participants to be recruited: Number: |  |  |

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| 1. **Funding**
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|  | **Delete as appropriate** | **Comment (if required)** |
| Is funding required for the study and if so, confirm the grant application status? | Yes/No |  |
| Are R+D finance administrator/s aware of the study (if applicable)? | Yes/No/NA |  |

*For all subsequent sections please complete column 2 with either Yes/no or √ and add any comment to column 3.*

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| 1. **Study team**
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|  |  | **Comment (if required)** |
| Are there any concerns with regards to sufficient availability of staff or resources being available for the study?  | Yes/No |  |
| Do the study team (CI and Principal Investigator (PI)) have previous research experience? | Yes/No |  |

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| 1. **Categorisation of study**
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| Is the category that has been chosen correct on the IRAS form?*NB For basic science involving a medicinal product ‘other’ should be selected.* | Yes/No |  |
| Does the researcher intend to make an application to the NIHR Clinical Research Network Portfolio? | Yes/No |  |
| Are review bodies appropriate to the study? (e.g. Ethics, MHRA if CTIMP and R+D) | Yes/No |  |

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| 1. **Indemnity**
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| Are the indemnity statements appropriate and consistent in the protocol, IRAS form and PIS? | Yes/No |  |

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| 1. **Purpose and design of the study**
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| Are the objectives detailed in the protocol and IRAS form? | Yes/No |  |
| Do any investigations require specific safety measures? Have these been addressed? | Yes/No |  |
| Does the protocol give justification for the research (affecting clinical care; knowledge; investigational development; commercial interest; educational)  | Yes/No |  |
| Is the justification of the research covered in the Information Sheet? | Yes/No |   |
| Is the nature of the intervention clearly described e.g. for new technique or device? | Yes/No |  |

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| 1. **Risks and ethical issues**
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| Do the inclusion/exclusion criteria reflect the nature of the intervention? Are contraindications covered if IMP or other intervention? | Yes/No |  |
| Are the investigations all necessary for the study? | Yes/No |  |
| Are any investigations invasive – has this been clearly covered in the information sheet? | Yes/No |  |
| Is there any significant normal clinical care to be withheld – is this reflected in the info sheet? | Yes/No |  |
| Have the risks and burdens to participants been considered i.e. inconvenience, painful procedures, use of information and samples? | Yes/No |  |
| Are there any risks to researchers? How will they be managed? | Yes/No/NA |  |

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| 1. **Recruitment and informed consent**
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| Are recruitment procedures appropriate? Who is screening the participants and are they part of the care team? | Yes/No |  |
| Are the informed consent procedures appropriate? | Yes/No |  |
| Vulnerable groups – are the management arrangements in place to cater for these? | Yes/No |  |
| Are the information sheet(s) and consent form(s) written according to HRA guidelines? | Yes/No |  |
| Is access by Sponsor (MKUH), MHRA (for CTs), ethics, relevant NHS Trust etc covered in the consent form? | Yes/No |  |
| Does the PIS/ICF cover access by commercial companies (if applicable)? | Yes/No/NA |  |
| Are samples ‘gifted’ to the Trust? | Yes/No/NA |  |

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| 1. **Scientific and statistical review**
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| Has the study been scientifically reviewed?  | Yes/No |  |
| Has there been a peer review (if appropriate)? | Yes/No |  |
| Has the study had a stats review by an appropriate person? | Yes/No |  |
| Are the primary and secondary outcomes clear? | Yes/No  |  |
| Is the sample size appropriate/achievable? | Yes/No |  |

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| 1. **Confidentiality**
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| Has confidentiality of personal data been addressed appropriately and in accordance with the Data Protection Act 2018? Note: Appropriate wording must be put in place for studies involving sites outside the EU | Yes/No |  |

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| 1. **Data Storage**
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| Is storage and access to data appropriate and in accordance with the Data Protection Act 2018? | Yes/No |  |

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| 1. **Incentives and payments**
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| Are incentives appropriate to study burden e.g. travel costs, any other payments? | Yes/No/NA |  |
| Are you aware of any conflict of interest? | Yes/No/NA |  |

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| 1. **GP involvement**
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| Is the level of GP involvement appropriate? | Yes/No/NA |  |

***Additional Information for specific applications e.g. Inclusion of medicinal products, ionising radiation, Human Tissue etc (complete if appropriate to the study being reviewed)***

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| 1. **Investigational Medicinal Products**
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| **Safety** | Yes/No/NA |  |
| Is a drug involved in the study?*If a drug is involved have the points below been considered with reference to the status of the drug:* * *First in man*
* *Unlicensed*
* *Outside indication or higher than normal dose*
* *Licensed or OTC – normal therapeutic dose and indication*
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| If the study is a Clinical Trial has a Clinical Trial Planning Form been completed? |  |  |
| Are the contraindications and side effects adequately described? |  |  |

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| 1. **Ionising Radiation**
 | Yes/No/NA |  |
| Has the exposure to radiation in the study been justified in the protocol? |  |  |
| Does the total exposure reported include both routine and research? |  |  |

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| 1. **Use of tissue samples**
 | Yes/No/NA |  |
| Is the section in the IRAS form consistent with Patient Information and protocol? |  |  |
| Do the PIS and ICF together ensure that appropriate consent will be obtained for using/keeping the samples? |  |  |

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| 1. **Adults Unable to consent**
 | Yes/No/NA |  |
| Has the inclusion of adults unable to consent for themselves been justified i.e. could the research question be answered without their inclusion? |  |  |
| Are information sheets and consent forms for the consultee available/ suitable? |  |  |

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| 1. **Children**
 | Yes/No/NA |  |
| Does your study include children? |  |  |
| Are the arrangements for seeking informed consent from a person with parental responsibility in place?   |  |  |
| Is the information provided to the participants appropriate and in a language/form understandable to the age range? |  |  |
| Are assent/consent procedures in place for the participants? |  |  |