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| Standard Operating Procedure **Sponsorship – gaining sponsorship and supporting sponsor oversight** | |
| **SETTING** | Trustwide |
| **AUDIENCE** | CI, PIs, Research staff including those involved in study design and co-ordination for studies sponsored by UHBristol. |
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| **Standard Operating Procedure (SOP)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Author: | Diana Benton | Role: | Head of R&I | | | Approved by: | Trust Research Group | | | | | Date for review: | November 2017 | | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Date reviewed | Version  number | Version Date | Effective Date | Reason for change | Author/Responsible person | Authorised by | | - | V1.0 | 21/10/15 | 03/11/15 | n/a | Diana Benton | Diana Benton | | 13/05/2016 | V2.0 | 07/04/16 | 13/05/16 | Major revision to sponsorship process to align with HRA processes and to ensure appropriate documentation of risk for CTIMPs. | Jess Bisset | Diana Benton | | November 2016 | V2.1 | 23/12/16 | 17/01/17 | Incorporation of consultation feedback | Jess Bisset | Diana Benton |  1. **Purpose**   The purpose of this document is to describe the role and responsibilities of a research sponsor and the process for applying for sponsorship and gaining agreement for UH Bristol to sponsor.   1. **Scope (areas/people in and out of scope should be defined)**   **In scope:** UHBristol sponsored research.  **Out of scope:** Research sponsored by other organisations.   1. **Abbreviations**      |  |  | | --- | --- | | **CI** | Chief Investigator | | **CTIMP** | Clinical Trial of an Investigational Medicinal Product | | **DMS** | Document Management System | | **GCP** | Good Clinical Practice | | **HRA** | Health Research Authority | | **IRAS** | Integrated Research Application System | | **MEMO** | Medical Equipment Management Organisation | | **MHRA** | Medicines and Healthcare products Regulatory Agency | | **NRES** | National Research Ethics Service | | **PI** | Principal Investigator | | **PoC** | Point of Contact | | **REC** | Research Ethics Committee | | **RGF** | Research Governance Framework for Health and Social Care | | **RMF** | Research Management Facilitator | | **RMO** | Research Management Office | | **RSS** | Research Support Services | | **SOP** | Standard Operating Procedure |  1. **Introduction**   All research conducted in the NHS must have a sponsor. This requirement is driven by the Department of Health’s Research Governance Framework for Health and Social Care and the Medicines for Human Use (Clinical Trials) Regulations (Clinical Trials regulations). The former applies to all research, and the latter applies to clinical trials of Investigational Medicinal Products (often referred to as drug trials).  A sponsor is an organisation which takes responsibility for the quality and conduct of a research study:  *“…the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting…”* [Research Governance Framework for Health and Social Care, second edition, 2005]  *“…the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial”*. [ United Kingdom Statutory Instrument 2004/1031 (The Medicines for Human Use (Clinical Trials) Regulations 2004]    **Sponsor responsibilities under the clinical trials regulations (CTIMPs)**  The responsibilities of a sponsor are described in the Clinical Trials regulations. They incorporate the following areas of legal responsibility:   * **Authorisation for clinical trials and research ethics committee opinion** * **GCP and the conduct of clinical trials** * **Pharmacovigilance** * **Manufacture and labelling of investigational medicinal products**   The responsibilities of a sponsor may be delegated. Any delegated responsibilities must be documented. Ultimately the sponsor remains accountable for all functions of sponsorship regardless of whether they have been delegated.  Further details relating to sponsor responsibilities can be found in the MHRA Grey Guide (ISBN 978 0 11 708107 9) and within the Clinical Trials Regulations (SI 1031) at this location: <http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf>  This SOP describes the UHBristol process for agreeing and maintaining sponsorship – i.e. applying for sponsorship and ensuring UHBristol sponsorship requirements continue to be met during the conduct of the research. The UHBristol suite of research SOPs describes the standards required to comply with legislation and the UHBristol procedures that must be followed to support compliance with the law. The legislation applies to Clinical Trials of Investigational Medicinal Products (CTIMPs). For other research the standards reflect good practice and should be applied in a proportionate and pragmatic way; they are underpinned by the Research Governance Framework, which is a requirement, but is not legally binding – see reference in section 7.     1. **Procedure**    1. **Determining if UHBristol is appropriate to sponsor**   The CI’s substantive employer usually takes on the role of sponsor. For clinical research, it may be appropriate for UHBristol to sponsor a study led by clinical academics practising in UHBristol and holding an honorary contract with the trust. For contract commercial research, the sponsor must be the funder. For research undertaken as part of a qualification, the university at which the student is registered should be the sponsor.  When a sponsorship application is submitted to UHBristol, it is reviewed to determine whether UHBristol is the most appropriate sponsor.  In order to make a sponsorship application, researchers should complete a **'Request for UHBristol to be Research Sponsor' form** (see appendix 1) and submit it with a **copy of the study protocol** via e-mail to [R&DSponsorship@uhbristol.nhs.uk](mailto:R&DSponsorship@uhbristol.nhs.uk).  Completed forms will be referred to the R&I Senior Management Team in order to assess whether it is appropriate for UHBristol to sponsor and continue through the sponsorship process. The Senior Management Team meets weekly, and provided the documentation is complete, a decision can usually be made and communicated to the applicant within seven working days. If UHBristol is not the most appropriate sponsor, the UHBristol Research Management Office (RMO) staff will liaise with partner organisation research management offices before proposing that they may be a more suitable sponsor.  There are a number of potential outcomes, which the UHBristol RMO will lead on:   * + - 1. agreement that UHBristol is a suitable sponsor and progression of an application       2. referral of the applicant to a partner organisation for sponsorship       3. referral of the applicant to their Higher Education Institution       4. referral of the applicant to a commercial funder   This SOP refers only to research which falls under option a, above.  If it is appropriate for UHBristol to sponsor the research, the researcher is sent an email containing the following information:   * Confirmation that a study record has been created on the EDGE research management system. * The name of the Research Management Facilitator (RMF) or Research Projects Manager who will take the study through sponsorship. * The R&I reference number that has been allocated. * Description of the next steps in the process, signposting to appropriate documents to support the applicant and any queries on the proposed research highlighted during senior management review.   1. **Agreeing sponsorship**   The next step is to agree sponsorship. A number of documents are required to provide assurance to the sponsor that the research can be carried out to the required standards. The sponsorship process is one which supports the collection or development of evidence to provide assurance, culminating in issue of a sponsor letter.   * + 1. **Chief investigator CV: confirmation that the CI is suitably qualified to lead the research**   The CI should include a current copy of his/her CV, along with any relevant training records. This may be a shortened CV (see Training SOP for template).   * + 1. **Study costing and evidence of funding: confirmation that resources are available to conduct the study**   All research incurs a cost. A statement of the approximate costs that will be incurred and how they will be met should be provided.  The costs can be attributed to a number of different categories, and the way in which the costs are met varies depending on the type and scale of research and how they are attributed. See ACoRD guidance here: <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>). Further information regarding costing can be found in the UHBristol Developing and Designing your Research SOP.    A **copy of the funding award letter** (if applicable) provides evidence that certain elements of the costs incurred will be met by the grant. The grant should usually meet all research costs, which may be incurred within the trust or by other organisations.  Elements of researcher time may not be costed, either because they are already funded and agreement has been reached to use the time for the study, or because the researcher expects not to be paid for the time spent carrying out the research. This should be stated.  **Evidence that arrangements are in place to meet excess treatment costs** should be provided; these may be in the form of email correspondence with service managers or other relevant personnel.  **Confirmation of likely NIHR portfolio eligibility or other arrangements for funding support costs must be provided**. It is likely that support costs will be incurred, and these can be met via the Clinical Research Network for NIHR portfolio studies, or via the funder (eg for commercial grants). Clinical Research Network support/delivery funding is allocated to the trust and supports the delivery of research in a variety of ways. This includes underpinning staff in pharmacy, radiology, lab medicine; funding research nurses, data managers and co-ordinators based in the clinical divisions and supporting programmed activities for recruitment into research. If the research requires support from a research team and/or one of the Trust's support departments (e.g. pharmacy, radiology, laboratory medicine or MEMO) please make contact with relevant individuals in those departments as soon as possible to discuss your requirements. This is to ensure there is the capacity and capability to deliver the research.  Each support department has a pro-forma which can be used to document those discussions and agreement that they can support the study. The current versions of the template pro-formas can be found on the R&I website: <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/templates-and-sops/templates/>  If the funder is not defined as an ‘eligible funder’ by the NIHR then support costs must be met by the grant or other means. For the definition of an ‘eligible funder’ see <https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support/>     * + 1. **Evidence of Peer Review: Confirmation that the quality of the study has been assessed**        1. **External funder review**: Evidence should be provided that review of scientific quality has been conducted as part of an external funding award, along with confirmation that reviewer comments have been addressed. In this case, no further peer review will be carried out.        2. **No external funder review/further review required:** If the study has not been reviewed by an external funder, or further review is considered desirable, the RMO will arrange for this to be undertaken prior to agreeing to act as sponsor. The peer review form is attached at appendix 3.     2. **Confirmation that there is capacity and capability to deliver the study within UHBristol and at other sites if relevant:** If the research is grant funded and has been through an extensive grant application process, it is likely that detailed discussions with other sites have taken place. The CI should confirm that sites are able to recruit the target number of patients and comply with the inclusion and exclusion criteria. For more complex studies, the CI should consider undertaking detailed feasibility activities, for example requiring PIs at other sites to review existing patient databases and ensure recruitment can be achieved. The CI should also confirm that there are staff in place within UHBristol and at other sites to screen, recruit and follow up study participants, complete and return the data, and that support departments can support the study at other sites (see also section 5.2.2). This will be documented by the use of a signed “Statement of Activities” (see <http://www.hra.nhs.uk/resources/> ) from other sites as part of the study setup process, but discussions can be initiated prior to that.     3. **Study Protocol: Confirmation that quality standards driven by the legislation and guidelines have been and will be met**. The study protocol is the key document for a piece of research. It should be detailed enough to describe how the research should be conducted, and to what standards. As sponsor, UHBristol has a set of standards which it requires its protocols and the conduct of research to meet; these are described through its suite of SOPs and standard text (<http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/templates-and-sops/>).   1. **The Review Process**   5.3.1 Risk Assessment Developing and completing a risk assessment is an ongoing process. For CTIMPs it begins during grant development, and for non-CTIMPs it starts during the sponsorship process.  **5.3.1.1 Risk Assessment for complex interventional trials (incl. CTIMPs)** If the grant for the proposed study is held by UHBristol and it is a CTIMP or it has been assessed by the Senior Management Team to be a complex interventional trial, the R&I Research Grants Manager will, in conjunction with the CI, start to document the risks of the trial using the Risk Assessment Template in Appendix 4 as soon as the grant is awarded. As the study passes through the sponsorship process the R&I Research Projects Manager will continue to complete the risk assessment by arranging a multi-disciplinary meeting with the following personnel;   * Chief Investigator (CI) * Principal Investigator (if different to the Chief Investigator at UHBristol) * Trial Co-ordinator * Research Nurse * Research Management Facilitator allocated to the trial * Support department representatives * Any other personnel deemed appropriate   All identified risks and mitigations will be agreed at this meeting and documented on the Risk Assessment Template. This will continued to be worked through until it is considered final by the CI and R&I Research Projects Manager as Sponsor Representative. The final version must be signed prior to issuing the green light, which must take place prior to any recruitment to the trial. Each time there are changes to the perceived risk and mitigating circumstances they must be agreed by the CI and Sponsor representative. The Risk Assessment Template must be updated, version controlled and re-signed by the appropriate signatories. This will be an ongoing process to document the risk throughout the life-cycle of the trial.  **5.3.1.2 Risk assessment for all other study types**. Once the documents (listed in section 5.2) have been received, the allocated RMF will carry out the Sponsorship assessment including a review of capability and capacity to deliver the research. This process is documented on the Research Management System EDGE using the applicable workflow. During this process the RMF will document identified risks and flag the study for monitoring required under the Monitoring and Oversight SOP.  **5.3.2 Study Set Up & Management Plan:** For CTIMPs and complex interventional trials, a ‘UHBristol Sponsor Study Set Up & Management Plan’ (SUMP), appendix 5, will be prepared by the Research Projects Manager alongside the completion of the risk assessment (as described in 5.3.1.1 above). If it is not possible to complete the SUMP during the multi-disciplinary review meeting, the Research Projects Manager will arrange to meet the trial co-ordinator and complete it as soon as possible.  The purpose of the SUMP is to document the management arrangements for the study and to ensure that it will be conducted in accordance with GCP and other relevant legislation. The ongoing activities for the management of the study will be discussed, assigned as appropriate, and documented, covering the period from the initial set-up to the close down of the study. The meeting is an opportunity to ensure that all parties are aware of their responsibilities before the study starts recruitment. The activities described in the SUMP are supported by UHBristol’s suite of research SOPs, which are mandatory for CTIMPs. .  **5.3.3 Issuing Sponsorship:** On completing the review process, a sponsorship letter is issued, accompanied by a ‘Statement of Chief Investigator Responsibilities’ document, which requires the CI’s signature to indicate agreement with the content, and must then be returned to the R&I office. It is at this stage, that the Trust may be named as the sponsor on subsequent applications to the MHRA, HRA and NRES. Requests for electronic authorisation by the sponsor on the IRAS system must be sent to [R&DSponsorship@uhbristol.nhs.uk](mailto:R&DSponsorship@uhbristol.nhs.uk)  A minimum of 6 weeks for non CTIMPs should be given from initial request for sponsorship before submitting an application to the HRA**. For CTIMPs a longer period of time should be allowed.** Please note that if your research has been fully supported by the UHBristol Research Grants Manager and team prior to grant submission, you should still apply for sponsorship; it may, however, be possible to shorten the 6 week lead time in these cases.  **5.4 After Sponsorship is issued: UHBristol's agreement to act as sponsor is not the green light for the study to commence, and is conditional on HRA approval and, where applicable, MHRA approval being in place. For all CTIMPs and where applicable complex interventional trials, the green light must have been given before patients are recruited.**  **5.4.1 Green light process to commence recruitment at UHBristol**: For CTIMPs and complex interventional trials, the R&I Research Projects Manager will review progress of completion of each applicable item on the SUMP. Any outstanding tasks requiring completion before trial commencement will be followed up by the Research Projects Manager or allocated RMF in conjunction with the research team and support departments. When all conditions have been met and all required tasks completed, the RMF, in conjunction with the Research Projects Manager, will issue sponsor green light for UHBristol as a site.  **5.4.1.1 Green light process for Trial Sites (CTIMP and complex interventional trials):** For multi-centre trials, a Site Initiation Checklist (appendix 8) must be completed by the research team for each participating site and returned to the allocated RMF. On receipt of the Checklist the RMF will ensure the required approvals are in place for that site (e.g. REC and Capacity and Capability confirmation) and once satisfied will issue green light for the site to open to recruitment. Please contact a member of the RMO for further information.  Please note that accredited clinical trials units may have their own green light processes. If a trial is under a trials unit’s management, and agreement is in place to do so, the unit’s green light processes may be followed.  **5.4.2 Sponsor assessment of amendments:** In line with the procedures described in the Gaining and Maintaining Authorisations SOP, all amendments for UHBristol sponsored research must be submitted to [R&DSponsorship@UHBristol.nhs.uk](mailto:R&DSponsorship@UHBristol.nhs.uk) for sponsor assessment prior to submission to HRA/REC/MHRA. For CTIMPs, the assessment will be recorded using the CTIMP Amendment Assessment Form for Sponsor (Appendix 6). This assessment will be carried out by a member of the Senior Management Team who will confirm whether the proposed amendment is acceptable and whether the amendment is substantial. For non CTIMPs this assessment will be carried out by a member of the Operations Team or for complex interventional trials the Research Projects Manager via email.  **5.4.3 Sponsor review meetings:** In order to monitor progress and compliance with applicable regulations, sponsor review meetings for active UHBristol CTIMPs may be carried out. These will be led by either the Research Projects Manager or allocated RMF and will involve the CI, PoC and any other appropriate personnel. Further detail of the processes involved in arranging and conducting a sponsor review meeting is provided in the work instruction in appendix 7.  **5.5 Investigator Oversight**  **Where UH Bristol is sponsor of a study the expectation is that the CI and PI(s) will maintain oversight as described in the UHBristol Investigator Oversight SOP. Although certain roles and duties within the trial may be delegated (e.g. to trials units and research nurses), the CI retains responsibility for those roles and duties and must maintain oversight of the delivery of the trial.**  **5.6 Monitoring and Oversight of Clinical Trials**  Under the RGF, UHBristol has a responsibility to monitor research conducted on its premises and under GCP to monitor studies which it sponsors. Please refer to the Monitoring and Oversight of Research SOP for further details.  There are a number of mechanisms for maintaining sponsor oversight of research. These include, but are not limited to, sponsorship representation or attendance at management and steering groups, routine communication with CIs, PIs and research teams and monitoring of the Study Management Plan (SUMP). At sponsorship, each study will be assessed on a case by case basis to determine whether a sponsor representative should attend oversight meetings (as defined above), and how regularly. This should be documented in the protocol and the SUMP.  **5.7 Publicity & Dissemination of the Research Findings**  **5.7.1 Publicising the Study:** Since September 2013 it has been a condition of REC approval that all clinical trials are registered on a publically accessible database. Accepted databases and further guidance can be found in the protocol template and guidance document produced by the HRA as referred to in the UHBristol Writing a Protocol to GCP SOP.  **5.7.2 Dissemination of Research Findings:** All research sponsored by UHBristol must have a plan for disseminating the findings of the study. This must be written into the research protocol; further guidance on this can be found in the protocol template and guidance document produced by the HRA as referred to in the UH Bristol Writing a Protocol to GCP SOP.  Transparency, registration and publication of research are core priorities to the HRA. More information on legal requirements as well as best practice can be found on the HRA website http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/transparency/   1. **Dissemination and Training in the SOP**    1. **Dissemination of this SOP**   **6.1.1 New SOPs and new versions of existing SOPs:** The Research Operations Manager is responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the Authorship, Review, Revision and Approval of Research Procedural Documents produced by Research & Innovation SOP. Internal Trust staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates. Staff who do not have access to the DMS are expected to check the website regularly for updates.  Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:   * Inclusion in the R&I e-bulletin (monthly) * Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade * Direct email to Chief Investigators of CTIMPs sponsored by UHBristol * Direct email to the Head of Research Governance at the University of Bristol (as relevant)   1. **Training in this SOP**   **6.2.1** All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.  **6.2.2** The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.   1. **References**   ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996) <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>  Medicines and Healthcare products Regulatory Authority (MHRA), 2014. Good Clinical Practice Guide. 3rd impression. TSO (The Stationary Office).  Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 <http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf>  Research Governance Framework for Health and Social Care <https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition>   1. **Appendices**   **Appendix 1 – Request for UHBristol to be Research Sponsor form**  **Appendix 2 – Work instruction for R&I office staff: Peer Review**  **Appendix 3 – Peer Review Form**  **Appendix 4 – Risk Assessment Template**  **Appendix 5 –UHBristol Sponsor Study Set Up & Management Plan**  **Appendix 6 – CTIMP Amendment Assessment Form for Sponsor**  **Appendix 7 – Work Instruction for Sponsor Review meetings**  **Appendix 8 – Site initiation checklist**  **IMPORTANT NOTE:**  This procedure has been screened for equality impact; it was not assessed as having adverse effects on any section of the community. | |
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| **RELATED DOCUMENTS** | Authorship, Review, Revision and Approval of Procedural Documents Produced by Research & Innovation SOP  Developing and Designing your Trial SOP  Writing a Protocol to GCP SOP  Gaining & Maintaining Authorisations SOP  Investigational Medicinal Product SOP (and associated pharmacy SOPs)  Research Training SOP  Investigator Oversight of Research SOP  Research Safety Reporting SOP  Monitoring and Oversight of Research SOP  Validation and Backup of Computer Systems used in Research SOP  Study Data  Clinical Trial Samples SOP  Key Trial Documents SOP  Archiving SOP  Research Contracts and Vendor Selection SOP |
| **QUERIES** | Research Operations Manager or Research Management Facilitators - Research & Innovation Department via 0117 342 0233. |

**Appendix 1- Request for UHBristol to be Research Sponsor form**

Request for UH Bristol to be Research Sponsor

Research team details

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| 1. |  |
| Name of Chief Investigator: |  |
| Name of Chief Investigator’s Employer\*: |  |
| Point of Contact details (if different from above): |  |
| Name of trials unit supporting the study (if applicable) \*\*: |  |

*\*If the Chief Investigator does not hold a substantive or honorary contract with UH Bristol, it is unlikely that it will be appropriate for UHBristol to act as Sponsor for the study.*

*\*\*If your study is a CTIMP and you are not supported by a registered trials unit, please contact us for detailed discussions before proceeding further (having submitted this form).This is in order to ensure that all risks of the research will be managed or mitigated through the proposed infrastructure.*

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| 2. |  |
| Will any part of this study contribute to an educational qualification? | \*Yes/\*\*No |
| **\*If yes:** | |
| Give details of qualification and higher education institution: |  |
| Supervisor name & position: |  |
| Supervisor email address: |  |
| **\*\*If no:** | |
| Is the research to be undertaken by a trainee or other equivalent junior member of staff? |  |
| Mentor name & position: |  |
| Mentor email address: |  |

*Where the main purpose of the research is to contribute to an educational qualification,* ***sponsorship is normally the responsibility of the awarding university****. For research below Doctoral level the academic supervisor should act as Chief Investigator and the student as Principal Investigator.*

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| Study Title: | | |
| Anticipated start date: | Anticipated end date: | Study Reference (if allocated):  / 201 / |
| Short summary of proposed research study (maximum 200 words): | | |
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| Statement of relevance/need for research: | | |
|  | | |
| Potential benefit/impact on patient care including how results of research will be translated into changing care (this can be local/wider changes): | | |
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**Study details**

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| 3. |  |
| How many patients do you plan to recruit? |  |
| Does this study involve an Investigational Medicinal Product (IMP) or an Investigational Device? | \*Yes/No |
| \*If yes: | |
| Who will be supplying IMP? |  |
| Have you discussed this with pharmacy? |  |

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| 4. |  |
| If this study does not involve an IMP, is this study interventional? | Yes/No |

*N.B In interventional studies patients are given a particular ‘intervention’ using for example a device, medicine, training, surgical technique or Cognitive Behavioural Therapy etc . Their outcomes are then compared to patients who did not receive the intervention.*

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| 5. |  |
| Is this a pilot or feasibility study?  Please state which. | Yes/No |
| **\*If yes** what are the future plans for this research, assuming the pilot/feasibility is successful: | |
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| 6. |  |
| Is this multi-centre? | Yes/No |
| **If yes:** | |
| How many sites are anticipated? |  |
| Will UH Bristol be the lead centre?  If no, which NHS Trust will be the lead centre? |  |
| Will any sites within the UK be Non NHS Sites? (If yes, please give details) |  |
| Are you in discussion with sites outside the UK?\*\* |  |

*\*\* UH Bristol is* ***not*** *able to Sponsor research with any sites outside the UK. If you wish to include sites outside the UK, please approach a different organisation for Sponsorship (eg. University).*

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| *7.* |  |
| *Have you discussed your protocol with a member of the proposed delivery team (i.e. Research Nurse) for deliverability?\** | *Yes/No* |
| *If yes please give details* |  |
| *Have you discussed your proposed study with any patient representatives? (i.e. PPI)* | *Yes/No* |
| *Please provide details (if no PPI has been carried out please justify why)* |  |

*\*Please note it is encouraged to discuss the feasibility of delivering a protocol with an experienced research nurse or other delivery team member. They will help to identify and resolve logistical issues early to aid delivery of the study to time and target. If you answer ‘no’ to this question, the R&I department will decide whether this is required.*

**Resource**

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| 7. |  |
| Which organisation(s) may/will be funding the study? |  |
| What is the status of the funding application?\* |  |
| If this study is unfunded please provide justification below why you believe the NHS and the Division should support this research: | |
|  | |

*\*Please note that we will be unable to issue sponsorship until confirmation of funding.*

***Our priority areas for research are: NIHR portfolio trials, NIHR BRU/C trials and all other funded (commercial and non-commercial) research. All research, however small, incurs costs (service support costs, treatment costs and/or overheads) which must be met by the division if there is no associated funding. If your study is unfunded and will incur costs that are not related to your time, it may reduce the likelihood of the Trust agreeing to sponsor your study. If you want to explore funding opportunities please talk to our grants manager; Elinor Griffiths on 0117 342 0233.***

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| 8. | Please specify resources to be used, approximate costs and how these costs will be met\*: | Type of cost (research, support, treatment cost)\*\*: |
| Staff time  *(usually research or support cost)* |  |  |
| Equipment  *(usually research cost)* |  |  |
| Consumables  *(usually research cost)* |  |  |
| Drugs and any other treatment costs  *(usually research or excess treatment cost)* |  |  |
| Facilities (e.g use of clinic space)  *(usually support, research or excess treatment cost)* |  |  |
| Registration & amendment fees (MHRA, ARSAC, public databases etc.)  *(usually research cost)* |  |  |
| Contract set up/review if applicable (non-NIHR portfolio study) |  |  |
| Any other resources |  |  |

*\*If study is fully funded then instead of completing the above table please send the relevant grant application with this form.*

*\*\*For further guidance on types of costs see:* [*https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research*](https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research)

**Divisional Support**

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| 9. |  |
| Will this study incur any excess treatment costs? If yes, please give details (excess treatment costs are the costs of the intervention/drug treatment under study versus those for normal treatment; this can be a negative value – i.e. a saving) | Yes/No/Not Applicable |
| **If yes**, is the Divisional Finance Manager of the Division in which treatment costs will be incurred aware of them? Please provide evidence. |  |
| Does your Divisional/Departmental Manager support this application? Please provide evidence. | Yes/No |

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| 10. | |
| Will this study require support from the following support departments: |  |
| Pharmacy? | Yes/No |
| Lab Medicine? | Yes/No |
| Radiology/Radiotherapy? | Yes/No |
| MEMO? | Yes/No |
| Other? (e.g. ECG/ECHO/Medical photography etc) | Yes/No |

**Scientific quality**

|  |  |
| --- | --- |
| 11. | Yes/No |
| Have you received any methodological or statistical advice from a research design/support service? (give details if applicable) |  |
| Have scientific/peer reviews of the protocol been undertaken? |  |
| If yes by whom? (please submit any evidence of peer review **with** this form when requesting sponsorship from UH Bristol) |  |

*Please note peer review should be carried out by appropriately qualified personnel with no conflict of interest with the research. R&I will determine whether peer review submitted is acceptable; if peer review is required please allow up to 4 weeks to process.*

Submission details:

* Please submit this form along with the most up to date version of the protocol to [R&DSponsorship@UHBristol.nhs.uk](mailto:R&DSponsorship@UHBristol.nhs.uk)
* You will then be sent an email from a member of the R&I team to acknowledge receipt of your application.
* Within one week you will receive further confirmation from a member of the R&I team confirming whether your study is eligible to be taken through our UH Bristol sponsorship process. If eligible, within this communication you will be sent a checklist of the full documentation required to process your sponsorship application.

Please note if your study is eligible to be taken through the sponsorship process you will need to allow 4 - 6 weeks before submitting to Ethics and HRA. For complex interventional trials, this process may take longer.

**Appendix 2** - **Work instruction for Research Management Facilitators: Peer Review**

**Statement**

The Trust’s peer review process conforms with the NIHR principles of high quality peer review: Independent, Expert, Proportionate. It will apply these principles to all types of research sponsored by the Trust.

Research ***projects*** which have already been independently peer reviewed as part of an open national funding award process will not be subject to additional peer review – for example NIHR RfPB, HTA. Where ***programmes*** of research have been reviewed prior to award, individual project review will be carried out in accordance with the principles above, for example NIHR PGfAR, BRU.

Hosted research is subject to peer review by its sponsor, and therefore does not fall under these processes.

**Process**

1. Ask the researcher to provide names of possible peer reviewers. [R:\Study resources\R&D approval resources\Project templates\Current Templates\Standard emails\scientific review request - para for inclusion in email to researchers 04.09.14.docx](file:///R:\Study%20resources\R&D%20approval%20resources\Project%20templates\Current%20Templates\Standard%20emails\scientific%20review%20request%20%20-%20para%20for%20inclusion%20in%20email%20to%20researchers%2004.09.14.docx)
2. Send out Scientific Review Form located in appendix 3 to this SOP to reviewers with the cover email [R:\Study resources\R&D approval resources\Project templates\Current Templates\Standard emails\EM5\_Science\_Review\_Request\_v3 20.08.14.rtf](file:///R:\Study%20resources\R&D%20approval%20resources\Project%20templates\Current%20Templates\Standard%20emails\EM5_Science_Review_Request_v3%2020.08.14.rtf)
3. Chase up Scientific Review, as necessary.
4. Send out copies of the completed scientific review request forms to the researcher and, as necessary, draw their attention to areas where further work is required or where concerns are raised. In some circumstances e.g. if reviewers state that the research is poorly designed and not of value to the NHS, the RMF may decide not to send out the forms but instead will feed back reviewer comments to the researcher in a different way. The RMF will usually suggest the researcher discusses the comments directly with the reviewer and/or the research lead within their clinical division if they want to proceed or want further support.

Appendix 3 – Scientific Review Form

|  |
| --- |
| INSTRUCTIONS FOR REVIEW |
| Please note that all boxes expand to accept as much commentary as required. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PROJECT DETAILS | | | | | |
| **Project Title** | |  | | | |
| **Principal Investigator** | |  | | | |
| **Reviewer** (name/title/institution): | |  | | | |
| Can the applicant contact you directly for further advice/clarification? *(We have found this to work well for applications which have a good research idea, but need further input.)* | | | | | Yes  No |
| **Important:** If you believe that there is a possible conflict of interest associated with reviewing this research proposal or if you believe you do not have the relevant level of expertise to provide an assessment of this proposal, please contact the Research Management Office before proceeding (Tel:0117 342 0223) or email: R&DSponsorship@UHBristol.nhs.uk | | | | | |
| **Please indicate your level of expertise in assessing this proposal:** | | | | | |
|  | High | | Medium | Low | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASSESSMENT CRITERIA | | | |  |  |  | |  |
|  | | | | | | | | |
| ***1. Relevance and originality of the research*** | | | | | | | | |
| **a) Is research in this area needed in the NHS?** | | | | Yes | No | Unclear | |  |
| *Please expand, e.g. importance of the research and whether it will lead to new understanding:* | | | | | | | | |
| **b) Is there similar work underway or published elsewhere?** | | | | Yes | No | Unclear | |  |
| *If ‘yes’ please give details and state whether the current project is still needed:* | | | | | | | | |
|  | | | | | | | | |
| ***2. Impact and dissemination*** | | | | | | | | |
| **a) Does the proposal have the potential to benefit patient treatment and care within the NHS?** | | | | Yes | No | Unclear | |  |
| *Please explain, outlining potential benefits and whether the research is likely to be applicable to the NHS in general or of local benefit only:* | | | | | | | | |
| **b) Is the dissemination plan adequate?** | | | | Yes | No | Unclear | |  |
| *Please expand, indicating how this could be further developed if appropriate:* | | | | | | | | |
| **c) Is the work likely to lead to a larger grant application?** | | | | Yes | No | Unclear | |  |
| *Please expand:* | | | | | | | | |
|  | | | | | | | | |
| ***3. Feasibility and study design*** | | | | | | | | |
| **a) Does the proposal clearly state the research question(s)?** | | | | Yes | No | Unclear | |  |
| *If no, please* *expand:* | | | | | | | | |
| **b) Is the proposed research (qualitative or quantitative) of high quality?** | | | | Yes | No | Unclear | |  |
| *Please* *comment on the strengths and weaknesses of the proposed research design:* | | | | | | | | |
| **c) Sample size and patient population (if the answer is ‘no’ to any of the questions below, please expand):** | | | |  |  |  | |  |
| *Are participant numbers realistic within the specified timeframe?* | | | | Yes | No | Unclear | |  |
|  | | | | | | | | |
| *Has an appropriate sample size calculation been performed?* | | | | Yes | No | Unclear | |  |
|  | | | | | | | | |
| *Is the planned statistical analysis suitable?* | | | | Yes | No | Unclear | |  |
|  | | | | | | | | |
|  | | | | | | | | |
| ***4. Study team and management*** | | | | | | | | |
| **a) Is the applicant suitably qualified to conduct the proposed study?** | | | | Yes | No | Unclear | |  |
|  | | | | | | | | |
| **b) If the principal researcher is inexperienced, does he/she have the background and support from within the team to develop the work?** | | | Yes | No | Unclear | | N/A | |
| *Please expand on whether or not all necessary support is available within the research team:* | | | | | | | | |
| **c) Can this project be delivered within the stated time frame?** | | | | Yes | No | Unclear | |  |
| *(if ‘no’ please expand):* | | | | | | | | |
| **d) Patient and public involvement (PPI): is there evidence of patient/public involvement in the study?** | | | | Yes | No | Unclear | |  |
| *Please comment on whether the level of PPI is appropriate, and if not, how this might be improved:* | | | | | | | | |
|  | | | | | | | | |
| ***5. Conclusion*** | | | | | | | | |
| **Do you have any concerns or doubts regarding the proposal?** | | | | Yes | No |  | |  |
| *If yes please summarise:* | | | | | | | | |
| **Please indicate your overall assessment of the quality of the proposal:** | | | | | | | | |
| Outstanding | Good | Adequate | | Poor | | | | |
| **In your opinion the proposed study should:** | | | | | | | | |
| Proceed as proposed  Proceed, although amendments recommended | | Re-submit with recommended amendments  Not proceed | | | | | | |
| **Details of any suggested amendments to the study proposal:**  *Please summarise* | | | | | | | | |
| **Any additional comments:** | | | | | | | | |
| **Signature:** | | **Date:** | | | | | | |

If returning the form by email, you will need to use a secure personally identifiable email account. Alternatively, the form can be signed and returned to the requesting Chief Investigator or Research Management Facilitator as a hard copy.

[R&DSponsorship@UHBristol.nhs.uk](mailto:R&DSponsorship@UHBristol.nhs.uk)

Research & Innovation, University Hospitals Bristol NHS Foundation Trust, Level 3, Education & Research Centre, Upper Maudlin Street, Bristol BS2 8AE

Appendix 4 – Risk Assessment Template

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Proposed study:** | | | | | | |
| **Proposed sponsor(s):** | | | | | | |
| **Risk assessment conducted by:** | | | | | | |
| **Date of current version of risk assessment:** | | | | | | |
| **Current version number of risk assessment:** | | | | | | |
|  | | | | | | |
| **1. SPONSORSHIP AND RESEARCH GOVERNANCE** | | | | | | |
| **Risk/Hazard** | **Likelihood (L/M/H)** | **Impact (L/M/H)** | **Concerns** | | | **(Recommendations for) mitigation and management** |
| Inadequate funding  *[How was costing generated? Are there any areas of concern - research/support/ETC?]* |  |  |  | | |  |
| Poor or inappropriate study design  *[how was final design reached - expert input?]* |  |  | *[eg power, outcome measures etc]* | | |  |
| Proposed eligibility review and sign off not completed by a medically qualified Doctor or Dentist as applicable. |  |  |  | | |  |
| Insurance/indemnity arrangements are weak/absent  *[What types of insurance/indemnity are in place].* |  |  |  | | |  |
| Failure to comply with regulations  *[E.g. is it a clinical trial, HTA regs, etc.]* |  |  |  | | |  |
| Lack of organisational accountability  *[Contracts – are the contractual arrangements adequate for the trial? Is there a clear delegation of responsibilities to a trials unit to co-ordinate the trial as applicable]* |  |  |  | | |  |
| Inadequate/poorly documented delegation to sites  *[how delegation will be documented for various types of sites]* |  |  |  | | |  |
| Poor quality control and quality assurance  *[Training, use of SOPs and guidance, appropriate delegation]* |  |  |  | | |  |
| Inadequate monitoring & auditing  *[Monitoring in line with bespoke study risk assessment, risk adapted plan for monitoring. What are the greatest risks of poor monitoring and auditing? How many sites? Data management systems?]* |  |  |  | | |  |
| Inadequate patient safety monitoring  *[oversight bodies, document in protocol - do what protocol says, SOP]* |  |  |  | | |  |
| Lack of engaged participating sites  *[Sites not interested in participating/may be slow to recruit – risk to achieving target recruitment]* |  |  |  | | |  |
| Archiving does not comply with requirements  *[SOPS, labelling of materials for archiving, ensure in site agreement etc.]* |  |  |  | | |  |
| **Understood and approved by** |  | | | | | |
| **Chief Investigator:** |  | | **Date:** | | |  |
| **Sponsor representative:** |  | | **Date:** | | |  |
| **Other:** |  | | **Date:** | | |  |
|  | | | | | | |
| **2. IMP RISK ASSESSMENT AND SAFETY MONITORING** | | | | | | |
| **2.1 IMP** | | | | | | |
| **EudraCT number:** |  | | | | | |
| **Type of study: (strike through those not applicable)** | **Type A: Comparable to the risk of standard medical care Type B: Somewhat higher than the risk of standard medical care Type C: Markedly higher than the risk of standard medical care** | | | | | |
| **Risk/Hazard of IMP/intervention and body system** | **Likelihood (L/M/H)** | **Impact (L/M/H)** | **Comments** | | | **Mitigation** |
|  |  |  |  | | |  |
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| **2.2 Arrangements for assessment of Adverse events** | | | | | | |
| *[details described in this section should be included in the protocol in full, or if the relevant section of the protocol has already been developed, it can be included here]* | | | | | | |
|  | | | | | | |
| **Understood and approved by** |  | | | | | |
| **Chief Investigator:** |  | | **Date:** | | |  |
| **Sponsor representative:** |  | | **Date:** | | |  |
| **Other:** |  | | **Date:** | | |  |
|  | | | | | | |
| **3. TRIAL RISK ASSESSMENT** | | | | | | |
| **3.1 IMP** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[eg off label use of drug, storage, labelling, accountability, administration,* |  |  |  | | |  |
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| **3.2 PATIENT SAFETY** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[e.g. invasive procedures and sampling, adverse response to IMP/intervention/procedure, eligibility, incorrect dosing]* |  |  |  | | |  |
|  |  |  |  | | |  |
|  |  |  |  | | |  |
| **3.3 PATIENT CONSENT, RIGHTS, CONFIDENTIALITY** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[e.g. vulnerable patient group, coercion, study design, data protection issues, data or relevant material leaving site]* |  |  |  | | |  |
|  |  |  |  | | |  |
|  |  |  |  | | |  |
| **3.4 RELIABILITY OF TRIAL RESULTS** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[e.g. source data, transcription to CRF, data entry, large volumes of data collection, complex data, multiple concomitant medications, samples, design of trial - timing of samples etc]* |  |  |  | | |  |
|  |  |  |  | | |  |
|  |  |  |  | | |  |
| **3.5 FACILITIES, EQUIPMENT, RESOURCES** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[e.g. facilities, staff availability, staff roles - clinical/research, staff training, ability to collect follow up data from other sites if patients transfer]* |  |  |  | | |  |
|  |  |  |  | | |  |
|  |  |  |  | | |  |
| **3.6 DOCUMENTATION, GOVERNANCE, GCP COMPLIANCE** | | | | | | |
| **Area** | **Risk/Hazard** | **Likelihood (L/M/H)** | **Concerns** | | | **Recommendations for mitigation and monitoring** |
| *[e.g. TMF, ISF, monitoring, oversight by sponsor or CI/PI]* |  |  |  | | |  |
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| **3.7 OTHER RISKS IDENTIFIED (ADD ADDITIONAL ITEMS AS REQUIRED)** | | | | | | |
| **Area** | **Risk/Hazard** | | | **Likelihood (L/M/H)** | **Concerns** | **Recommendations for mitigation and monitoring** |
|  |  | | |  |  |  |
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|  |  | | |  |  |  |
| **Understood and approved by** |  | | | | | |
| **Chief Investigator:** |  | | **Date:** | | |  |
| **Sponsor representative:** |  | | **Date:** | | |  |
| **Other:** |  | | **Date:** | | |  |

**Appendix 5**

UH Bristol Sponsor Study Set Up & Management Plan

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Full Title of Trial** |  | | | | |
| **Short Title / Acronym** |  | | | | |
| **EudraCT Number (if applicable)** |  | **UH Bristol R&D Number** |  | **IRAS ID** |  |
| **Chief Investigator** |  | | **Funder** |  | |

|  |
| --- |
| This document is intended to lay out the management plan for the above study.  The tasks for the management of the study are outlined below and cover the period from the initial set-up to the close down of the study. Each task is to be assigned to the appropriate personnel. It is then their responsibility to undertake the task within the target time frame specified.  Where the study has participating sites, the term ‘Lead Site’ refers to UH Bristol. Where a study involves the set-up of participating sites, this management plan must be used in conjunction with the “Site Initiation Checklist”.  For CTIMPs, items marked \* are a legal requirement under the Medicines for Human Use Clinical Trials Regulations (2004). |

|  |
| --- |
| **For STATUS: C = Completed; IP = In Progress; NS = Not started; N/A = Not Applicable** |

1. *Regulatory Approvals*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \*Obtain Research Ethics Committee (REC) approval  <http://www.hra.nhs.uk/research-community/applying-for-approvals/research-ethics-committee/> |  |  |  |  |
| \*Prepare and submit MHRA application for Clinical Trial Authorisation for CTIMP  <http://www.hra.nhs.uk/research-community/applying-for-approvals/medicines-and-healthcare-products-regulatory-agency> |  |  |  |  |
| Prepare and submit MHRA application for a Notice of No Objection for Medical Device Research <http://www.hra.nhs.uk/research-community/applying-for-approvals/medicines-and-healthcare-products-regulatory-agency-mhra-notice-of-no-objection-medical-device-research/> |  |  |  |  |
| Prepare approval applications from other relevant bodies (e.g. ARSAC, NIGB/CAG, HTA) if applicable |  |  |  |  |
| Register trial with appropriate registration scheme(s) (clinicaltrials.gov, ISRCTN, UKCRN Portfolio) |  |  |  |  |
| Obtain HRA approval  http://www.hra.nhs.uk/research-community/ |  |  |  |  |

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| **For STATUS: C = Completed; IP = In Progress; NS = Not started; N/A = Not Applicable** |

1. *Contractual and Financial Arrangements*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ensure appropriate contractual agreements in place e.g. Site Agreement(s), Pharmacy Technical Agreements, collaboration agreements |  |  |  | [*List agreements required]* |
| Arrange sign off of the University of Bristol and UH Bristol Framework Agreement (if study involves UoB staff and there is not a separate collaboration agreement) |  |  |  |  |
| Manage and keep record of trial finances, in liaison with the appropriate Management Accountant, specifically in relation to invoicing arrangement e.g. for support depts. |  |  |  |  |

1. *Support Department approval – Pharmacy Tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
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| Obtain sign-off from the pharmacy department.  <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-department-authorisation/> |  |  |  |  |
| Identify supply of Investigational Medicinal Product(s) (IMPs), in collaboration with the relevant UH Bristol pharmacy departments |  |  |  |  |
| \* Ensure IMP is provided, imported and labelled in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, in liaison with pharmacy |  |  |  |  |
| Completion of pharmacy manual (or NIHR template) to record all relevant pharmacy requirements at the lead site. |  |  |  |  |
| Share pharmacy manual with R&I as sponsor and the study team |  |  |  |  |
| Approach pharmacy departments at the participating sites to carry out feasibility (if applicable) |  |  |  |  |
| Add annex to site agreements to document the required activities undertaken by the participating site’s pharmacy department (if applicable) |  |  |  |  |
| \* Set up of pharmacy file (to include associated study SOPs and Protocol) |  |  |  |  |
| \*Put in place suitable storage arrangements for IMP. Where IMP is to be stored outside pharmacy complete Pharmacy risk assessment. |  |  |  |  |
| Put arrangements for temperature monitoring in place |  |  |  |  |
| Train pharmacy personnel (as appropriate) and research team at lead site with appropriate use of IMP as described in protocol and other product information. Document training on training logs and file in accordance with Essential Research Documents SOP. |  |  |  |  |
| For dispensing put study prescriptions in place |  |  |  |  |
| \*Put arrangements in place for QP certification of IMP (if applicable) |  |  |  |  |
| \*Put arrangements in place for QP release (if applicable) |  |  |  |  |
| Put accountability records in place (and set up system) |  |  |  |  |
| Put system in place for destruction/return of IMP – (including participating site arrangements if applicable). |  |  |  |  |
| Put and document unblinding arrangements in place (if on call pharmacists to carry out unblinding) |  |  |  |  |
| Document process for out of hours cover (if applicable) |  |  |  |  |
| Carry out a test run of emergency unblinding and out of hours cover. Ensure this is documented. |  |  |  |  |

1. *Support Department approval - MEMO (Medical Equipment Management Organisation) Tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Obtain authorisation from UH Bristol MEMO <http://www.uhbristol.nhs.uk/for-clinicians/memo/memo-authorisation/> |  |  |  |  |
| Confirm whether MHRA approval is required (use this link for guidance) and document any correspondence with the MHRA <http://www.mhra.gov.uk/Howweregulate/Devices/index.htm> |  |  |  |  |
| Put in place a tailored maintenance plan (if needed); |  |  |  |  |
| Take responsibility for oversight and compliance of any other MEMO conditions |  |  |  |  |
| Put in place and document arrangements for requesting replacements and/or new supplies |  |  |  |  |
| Put in place and document storage arrangements for equipment and/or consumables |  |  |  |  |

1. *Support Department approval – Labs Tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

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| Obtain authorisation from the labs (may also require histopathology sign off or agreement from external labs if applicable). List each lab being used.  <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-department-authorisation/> |  |  |  |  |
| Create sample labels and put copies in Trial Master File |  |  |  |  |
| Arrange and document sample storage in compliance with any HTA requirements or temperature monitoring as applicable |  |  |  |  |
| Arrange and document sample transfer- including transfer from clinics/theatres to labs *[study specific SOP may be advisable].* In line with section 2 of this SUMP put MTA in place if required |  |  |  |  |
| Make arrangements and document retrieval of histopathology samples (as applicable). |  |  |  |  |
| Write Lab manual. This should include local lab reference ranges for participating sites (if applicable). Refer to Research Samples SOP. |  |  |  |  |
| Make arrangements and document destruction/storage/transfer of samples on study completion |  |  |  |  |

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| **For STATUS: C = Completed; IP = In Progress; NS = Not started; N/A = Not Applicable;** |

1. *Support Department approval - Radiology and Radiotherapy Tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Obtain authorisations for radiology and radiotherapy requirements for the study including IRMER, Medical Physics and ARSAC.  <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-department-authorisation/> |  |  |  |  |
| Put and document process in place for requesting imaging/radiotherapy. |  |  |  |  |
| Put and document procedure in place with PACs for anonymisation of images if scans are to be sent externally |  |  |  |  |
| Obtain authorisations for any external imaging to take place e.g. PET scans |  |  |  |  |
| Complete Project Specification Form and obtain CRIC Agreement (if applicable) |  |  |  |  |

1. *Support Department approval- any other (e.g. ECG, Medical Imaging, CRIC etc) Tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Obtain authorisations from (as required)  *Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |  |  |  |
| Obtain authorisations from (as required)  *Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |  |  |  |
| Obtain authorisations from (as required)  *Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |  |  |  |

|  |
| --- |
| **For STATUS: C = Completed; IP = In Progress; NS = Not started; N/A = Not Applicable; D = Discussed** |

1. *Safety recording and reporting*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Put up to date copy of Safety reporting SOP in site file and ensure process is in place for referring to most current version. |  |  |  |  |
| \*Put arrangements in place to record all adverse events |  |  |  |  |
| Train study team in safety reporting procedure and document training. |  |  |  | *[document current version of applicable SOP]* |
| Trial Management Group or applicable other set up to maintain oversight of all reported SAEs |  |  |  |  |
| Put in place process to ensure all Serious Adverse Events (SAE) at the lead site and all participating sites, other than those specified in Protocol as not requiring immediate reporting, are recorded, assessed and reported in line with the regulatory requirements and Trust policy |  |  |  | *[Remind during SUMP meeting that all SAEs must be notified to Sponsor within 24 hours of team becoming aware of event]* |
| Put in place process to ensure all SAEs at the lead site and all participating sites are reviewed by an appropriate committee for monitoring trial safety (if applicable) |  |  |  |  |
| \*Put in place process to ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are recorded, assessed and reported to the Research Management Office in accordance with the regulatory requirements and Trust policy in order to permit onward reporting to authorities within timelines. |  |  |  |  |
| \* Confirm arrangements to enter SUSARs into the European database are in place. |  |  |  |  |
| \* System set up to ensure investigators at lead site and at participating sites are, at all times, in possession of the current relevant safety information, including SUSARs, for the trial |  |  |  |  |
| Reminders put in place to ensure Annual Safety Reports (ASRs and DSURs) and progress reports are submitted to the MHRA and REC within the required timescales and copies provided to the Research Management Office |  |  |  |  |
| System in place to promptly inform the MHRA, REC, the Research Management Office, the research team at the lead site and the PIs at other sites of any urgent safety measures taken to protect participants |  |  |  |  |

1. *Preparation for additional sites or tick box if N/A*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Identify appropriate participating sites and suitably qualified PIs at these sites |  |  |  |  |
| Obtain sponsor authorisation for the number and location or participating sites |  |  |  |  |
| Submit paperwork to participating sites for capability and capacity review |  |  |  |  |
| Keep records of capability and capacity confirmation in TMF from each NHS organisation involved in the research |  |  |  |  |
| Conduct initiation visits at participating sites |  |  |  |  |
| Issue green light to recruit |  |  |  |  |

|  |
| --- |
| **For STATUS: C = Completed; IP = In Progress; NS = Not started; N/A = Not Applicable** |

1. *Study Team*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Check HR requirements for study team and arrange research passports, contracts or letters of access as required  <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/research-passports/> |  |  |  |  |
| Train research team in use of trial-specific standard operating procedures |  |  |  |  |
| Put process in place to ensure and document whether members of the research team at UH Bristol are appropriately qualified by education and experience to undertake their role(s) |  |  |  |  |
| Put adequate supervision arrangements in place for students and new researchers |  |  |  |  |
| Put process in place to ensure and document that core research team members have completed ICH GCP training (within previous 3 years) |  |  |  |  |

1. *Study Admin*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Design case report forms and database |  |  |  |  |
| Sign off the finalised Case Report Form |  |  |  |  |
| Develop appropriate QC and validation process for data |  |  |  |  |
| Complete Data Management Plan |  |  |  |  |
| Develop trial-specific standard operating procedures (if applicable) |  |  |  |  |
| Arrange and document randomisation procedures |  |  |  |  |
| Ensure Trial Master File (TMF), Investigator Site Files and associated documentation is complete, accurate and legible in accordance with the Essential Research Documents SOP |  |  |  |  |
| Maintain a record of patient recruitment and report recruitment to the NIHR (portfolio studies only) and to the R&I Department in line with Trust requirements |  |  |  |  |
| Enter recruitment data to the EDGE database and keep the EDGE study record up to date  [www.edge.nhs.uk](http://www.edge.nhs.uk) |  |  |  |  |

1. *Research Delivery*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ensure trial is managed, monitored and reported as agreed in the protocol and main contract with funder and collaboration agreements |  |  |  |  |
| Train research team in all applicable Sponsor SOPs and any updates and ensure this is documented |  |  |  | *[List applicable Sponsor SOPs here and document where trials unit/research team have own SOPs they wish to use instead]* |
| Monitoring plan finalised |  |  |  |  |
| Report suspected breaches of protocol, ICH GCP and research misconduct and fraud, in accordance with relevant policies and guidelines and ensure all are submitted to Sponsor for assessment of seriousness and required reporting. |  |  |  |  |
| Submit progress reports to funder and HRA |  |  |  |  |

1. *Amendments*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Send protocol amendments to sponsor for prior agreement prior to submission to REC and MHRA for approval and implementation |  |  |  | *[Agree Sponsor contact person to send amendments to]* |
| Prepare and submit substantial amendments to the MHRA, REC  <http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/submitting-amendments/> |  |  |  |  |
| Arrange amendments and/or extensions with the funder as necessary following discussion with R&I. |  |  |  |  |
| Obtain continuing confirmation of capability and capacity review at participating sites following amendments |  |  |  |  |
| Ensure participating sites have latest versions of study documents as approved by the MHRA and REC |  |  |  |  |

1. *Study Completion*

| **Tasks** | **Responsible personnel** | **Target completion** | **Status** | **Comments** |
| --- | --- | --- | --- | --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Notify regulatory authority(ies) and relevant REC if trial suspended or terminates early |  |  |  |  |
| Notify regulatory authority(ies) of the end of the trial |  |  |  |  |
| Ensure all trial records at each site are archived appropriately on conclusion of the trial and retained in accordance with current regulations and guidelines |  |  |  |  |
| Initiate and coordinate review and submission of abstracts, posters and publications |  |  |  |  |
| Submit final report to all applicable regulatory authorities and Sponsor |  |  |  |  |

|  |
| --- |
|  |

Date of Initial meeting \_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of CI \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I confirm that updates to the SUMP may be signed off by the Trial Manager on my behalf Yes 🞎 No 🞎

Signed \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Sponsor’s Representative \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Trial Manager (where applicable)

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_

**Appendix 6**

**CTIMP Amendment Assessment Form for Sponsor**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Amendment Assessment Form For CTIMPs** | | | | | | | | | |
| Trial name / Acronym: | |  | | | | | | | |
| R&I reference: | |  | | | EudraCT number: |  | | | |
| Chief Investigator: | |  | | | | | | | |
| Co-Sponsor: | | N/A | | | | | | | |
| CURRENT Protocol version no & date | |  | | | | | | | |
| AMENDED Protocol version no & date | | N/A | | | | | | | |
| Reason for amendment: | | Change to study procedures or documentation (list revised documents below)  Urgent safety measure already implemented  Notification of temporary halt in the trial  Request to re-start the trial | | | | | | | |
| Additional revised documents (list any revised CT application, PIS/CF, questionnaires etc. provided for Sponsor review) | | Document | | | | | | New Version number | Date |
|  | |  | | | | | |  |  |
|  | |  | | | | | |  |  |
|  | |  | | | | | |  |  |
|  | |  | | | | | |  |  |
| Does this review address revisions requested by Sponsor from an earlier review? | | Yes. If yes please give the date previous amendment form submitted:\_ \_ / \_ \_ \_ / \_ \_ \_ \_  No  N/A (first Sponsor review of this amendment) | | | | | | | |
| **Description of amendment:** *(Including actions taken from any previous Sponsor comments)* | | | | | | | | | |
|  | | | | | | | | | |
| **Outcome of Sponsor Review** *(For completion by designated Sponsor representative):* | | | | | | | | | |
| Sponsor in agreement with amendment | | | | | | | | | |
| Sponsor in agreement with amendment, but minor revisions requested before signature (please give details below)  Details of requested changes: | | | | | | | | | |
| Sponsor requires major revision of protocol and/or supporting documents (please give details below and continue on a separate page if necessary)  Details of requested changes: | | | | | | | | | |
| Sponsor requires this amendment to be sent to:  **HRA YES  NO**  **REC YES  NO**  **MHRA YES  NO**  **OTHER \_\_\_\_\_\_\_\_(specify)\_\_\_\_** | | | | | | | | | |
| **Amendment classification:** *(For completion by designated Sponsor representative)* | | | | | | | | | |
| Substantial | | | **Category of substantial amendment** *(tick as many as appropriate)* | | | | | | |
|  | | | A The safety or physical or mental integrity of the participants of the trial | | | | | | |
|  | | | B The interpretation of scientific documents / value of the trial | | | | | | |
|  | | | C The quality or safety of any investigational medicinal product or placebo used in the trial | | | | | | |
|  | | | D The conduct or management of the trial | | | | | | |
|  | | | E Change or addition of Principal Investigator(s) or Co-ordinating Investigators | | | | | | |
|  | | | F Change of Sponsor, legal representative | | | | | | |
|  | | | G Change / addition of new sites | | | | | | |
|  | | | H Change in responsibility for major trial-related duties | | | | | | |
|  | | | I Significant changes in patient literature | | | | | | |
|  | | | Other, please specify: | | | | | | |
| Non-substantial | | | **Justification:** | | | | | | |
| Comments & any actions required: | | |  | | | | | | |
| **Signature of Sponsor representative confirming review of amended documents:** | | | | | | | | | |
|  | Name | | | Signature | | | Date | | |
| Sponsor representative: |  | | |  | | | \_ \_ / \_ \_ \_ / \_ \_ \_ \_ | | |

References

1. SOPs for RECs V6.1 Jan 2015 (see Section 6 and Appendix C)

http://www.hra.nhs.uk/resources/research-legislation-and-governance/standard-operating-procedures/

1. The Medicines for Human Use (Clinical Trials) Regulations 2004 No. 1031 (see Part 3 Regulations 22 – 25)

<http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf>

**Appendix 7 - R&I Department Work Instruction for Sponsor Review Meetings**

For UH Bristol sponsored CTIMPs an assessment will be made annually (or more frequently if necessary) regarding whether a sponsor review meeting is required. Whether a sponsor review meeting is required depends on the progress of the study, feedback from staff, the risks of the study and how the study conduct is being managed. The decision will be made by a member of the senior R&I management team. This document describes the process for arranging and carrying out a review meeting and is intended as a work instruction for the Research Management Facilitator (RMF) allocated to the trial or the Research Projects Manager (RPM). The name of the RMF allocated to a trial is recorded on the Research Management database.

1. The RMF/RPM will record on the research management system (EDGE) the date of the sponsor review meeting and will keep a record of when the next review meeting is due.
2. Two months in advance of a review meeting due date, the allocated RMF/RPM will contact the Chief Investigator, point of contact and any other applicable staff personnel (i.e. research nurse) to arrange a date for the meeting.
3. Once a date is arranged, the RMF/RPM will arrange a suitable meeting venue in liaison with the point of contact and will request an appropriate member of the R&I senior management team to attend.
4. The RMF/RPM will contact any support departments involved in delivery of the trial requesting them to raise any issues to be brought to the review meeting. It is not mandatory for support departments to attend the meeting but the RMF/RPM should extend the invitation.
5. The RMF/RPM will obtain a current update of finances within the trial. For UH Bristol sponsored studies where UH Bristol is holding a grant they may need to contact [Elizabeth.Wilkinson@UHBristol.nhs.uk](mailto:Elizabeth.Wilkinson@UHBristol.nhs.uk) If the RMF is unclear where the finances are being held, the RMF/RPM will need to talk to the Research Grants Manager in R&I.
6. The RMF/RPM will create an agenda for the meeting which they will send to the attendees 2 weeks prior to the meeting date. This will be done in liaison with the senior manager attending the meeting and reviewing the study progress to date. As an example the agenda should include the following items (where applicable):

-Brief update on study progress

-Summary of any issues

-Review of Study Set Up and Management Plan (SUMP)

-Finances

-Sites

-IMP management and other support department issues

-Recruitment

-Data management (compliance with study data management plan)

-Monitoring

-CI training (refer to CI training slides)

-R&I SOPs and any updates

-AOB

1. The RMF/RPM will need to prepare in advance of the meeting the following:

-Print out a sponsor review meeting attendance record

-Bring copies of the SUMP originally completed during set up of the trial and if any sponsor review meetings have already taken place the updated notes from these

-Print out/send to point of contact CI/PI training slides to use

-Bring latest version of trial Protocol

-Bring a list of sites (where applicable)

-Print out of EDGE record (including recruitment details and end date)

-Up to date details of all relevant R&I SOPs

8. During the meeting the senior manager will chair the meeting whilst the RMF/RPM takes meeting notes. The RMF/RPM will ensure any CI/team training carried out as part of the meeting is documented on the sponsor training log and the attendance log at the meeting is completed.

9. After the meeting the RMF/RPM will circulate the meeting notes within 2 weeks of the meeting and save these within the electronic study folder on the R&I R Drive.

**Appendix 8** - **UH BRISTOL SPONSORED STUDIES - SITE INITIATION CHECKLIST**

|  |
| --- |
| **Trial title:**  **EudraCT:**  **Site name/address:**  **PI contact details:**  **Point of Contact details (if different from PI):**  **Date of site initiation visit/telephone call:** |

1. **Regulatory Approvals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| REC approval for addition of site |  |  |  | *Ensure copies of REC approval in place at site* |
| R&D approval at site |  |  |  | *Ensure R&D approval has been given and copies of approval letter filed at site* |
| Regulatory approval from MHRA |  |  |  | *Ensure copies of MHRA approval letters provided to site (include device & IMP letters)* |
| Any other applicable approvals  Please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |

1. **Site Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| Qualification and experience of PI |  |  |  | *Please document relevant qualification and experience of PI- this will confirm appropriateness of PI at the site.* |
| CV’s for all site study staff stored in site file |  |  |  | *Review whether CVs for all site study staff are stored in the site file and remind team that any new members of staff will need to provide their CV for the site file.* |
| GCP training record for all study staff stored in site file (\*update required every 3 years) |  |  |  | *Review whether GCP training in place for all study staff (those with an active role in the study) and remind site staff that UH Bristol as sponsor require GCP training to be updated every 3 years.* |
| Training of research team on protocol/study specific procedures |  |  |  | *List all study specific procedures and train relevant site staff during meeting. If too much training to be undertaken arrange a separate meeting in order to carry this out. Make sure ALL training is recorded on training logs.* |

1. **Pharmacy Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| Pharmacy manual provided to site |  |  |  | *A Pharmacy manual may not be applicable however any paperwork associated with the IMP needs to be provided to the site and this paperwork to be located in their study file. The site hospital pharmacy needs to also have a copy of any IMP related paperwork* |
| SOP/documented process in place for supplying IMP to site |  |  |  | *Confirm arrangements for how IMP will be supplied to site- if no study specific SOP in place to describe this – note this process down in this site initiation checklist.* |
| Process in place at site for QP sign off on receipt of IMP if applicable |  |  |  | *Discuss with site process of IMP receipt at site and ‘sign off’ by pharmacy before release to study team. Note process down here. Remind team that all processes must be documented and signed by relevant individuals at the site (ie pharmacist to trial team member)* |
| Storage and dispensing arrangements of IMP at site |  |  |  | *Document what storage and dispensing arrangements will be in place. Please note storage must be secure – if any temperature conditions required (ie store at room temperature or not above 40degrees Celsius) note that here and ensure site staff are aware of requirements.* |
| Agreed and documented process for return or destruction of unused IMP |  |  |  | *Document what will happen at end of trial with unused IMP – ensure pharmacist at site is aware of process and who is responsible for ensuring process is followed (PI)* |
| Pharmacy at site in agreement to comply to protocol and GCP? |  |  |  | *Confirm Pharmacy at site agree to comply to study protocol and GCP* |
| Drug administration procedures |  |  |  | *Document procedure and confirm site understand and will comply with appropriate procedures.* |

1. ***Device trials***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| Relevant support department authorisation |  |  |  | *Ensure that any site support department are aware of device and happy for it to be used within the trust (e.g. at UH Bristol MEMO would be consulted)* |
| Technical/maintenance manual provided to site |  |  |  | *Ensure all paperwork associated with the device is provided to site. If any training is required ensure this is provided to relevant site staff and documented on the training log.* |
| SOP/documented process in place for supplying consumables to site |  |  |  | *If no SOP in place – document here how consumables to be provided to site* |
| Storage arrangements of equipment and/or consumables at site |  |  |  | *Review with site staff the proposed storage arrangements and ensure these are appropriate (i.e. securely stored, restricted access/use etc) and document these here.* |
| Agreed and documented process for return of equipment and unused consumables |  |  |  | *Note here what will happen to equipment at the end of the study.* |

1. ***Other Study Specific Procedures***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| Sample collection procedures including frequency and exact time points of when samples to be taken |  |  |  | *Review with site staff sample collection procedures as per protocol.* |
| Sample Logs |  |  |  | *Ensure sample logs are provided to site staff for use to record sample collection as applicable* |
| Lab kits provided to/available at site? |  |  |  | *Document whether any kits provided (or to be provided) and process in place for this* |
| Agreement from site lab staff to undertake the study (if applicable) |  |  |  |  |
| Any other support department procedures specified (enter specific procedures if applicable) |  |  |  | *e.g. IM&T specific procedures (for supporting data entry of an electronic database)/ radiology if scans are required.* |

1. ***Informed Consent and Enrolment***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| Informed consent procedures |  |  |  | *Review with site staff what informed consent procedures should be followed during the study and ensure that all have fully understood. For CTIMP trials ensure that eligibility review of the patient is carried out by a medically qualified member of staff and that this is clearly documented prior to the patient’s participation in the trial* |
| Randomisation procedures |  |  |  | *Review with site staff what randomisation procedures should be followed. If an SOP or work instruction is in place for this provide this to site staff. Make sure they know how to randomise appropriately.* |
| Unblinding procedures |  |  |  | *Review unblinding procedures – e.g. in what circumstances to unblind and what is the process that needs to be followed* |
| Code break envelopes received at site (if applicable) |  |  |  |  |
| Randomisation log (and specify required location if study team are to be blinded) |  |  |  | *Discuss with site staff where and how randomisation log is to be kept and if staff members are unblinded how to avoid accidently unblinding* |
| Recruitment monitoring |  |  |  | *Discuss site target and agree appropriate route for monitoring recruitment – note here.* |

1. ***Safety Reporting***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| AE/SAE reporting process documented and agreed by site |  |  |  | *Provide site with copy of UH Bristol Safety Reporting SOP. Ensure site staff fully understand safety reporting procedures for this trial and have all of the relevant contact details for the CI, lead site and Sponsor to report safety events or other safety concerns* |
| Toxicity parameters |  |  |  |  |
| Provide emergency contact details of sponsor |  |  |  |  |
| Protocol deviation reporting procedures |  |  |  | *Review process with site staff and timelines. All deviations should be reported within 24 hours to the Sponsor and CI. The Sponsor will review whether the deviation would be considered a serious breach and any onward reporting required. Serious breaches have to be reported to the regulatory authorities within 7 days.* |

1. ***Monitoring Arrangements***

*Please verify with site which of the following monitoring visits will take place*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **Projected Visit Date** | **Actions/Comments** |
| FPFV Visit/Call |  |  |  |  |
| Protocol compliance site visits |  |  |  |  |
| Self-Monitoring |  |  |  |  |
| Close Out Visit/Call |  |  |  |  |

1. ***Investigator Site file***

*Please check the following documents are stored in the site file*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/Verified** | **Yes** | **No** | **N/A** | **Actions/Comments** |
| UH Bristol site file template provided to site |  |  |  |  |
| Signed Site Agreement with target recruitment included |  |  |  |  |
| Final study protocol, signed and dated by PI |  |  |  | Version: |
| Financial arrangements (including invoicing procedures) |  |  |  |  |
| Other contractual agreements (please specify) |  |  |  |  |
| Completed delegation log |  |  |  | *(ensure PI signs against each delegated study staff member’s record)* |
| PIS  *List* |  |  |  | Version: |
| Informed Consent forms  *List* |  |  |  | Version: |
| GP Letters |  |  |  | Version: |
| Case Report forms |  |  |  |  |
| Data management procedures (including anonymisation procedures and compliance with data protection act) |  |  |  |  |
| Describe Source Data Verification checks required to be completed by site |  |  |  |  |
| Investigators brochure or SmPC |  |  |  | Version:  NB. Discuss best process of who to provide updates of the IB or SMPC to |

|  |
| --- |
| **Any outstanding issues which need to be resolved before green light is issued:** |
|  |

|  |
| --- |
| **Trial Manager: (where applicable)**  **Signature:**  **Print name:**  **Date:**  **Sponsor’s representative:**  Signature:  Print name:  Date: Signed by e-mail: ⬜  **Chief Investigator:**  Signature:  Print name:  Date: Signed by e-mail: ⬜ |