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| St George’s Joint Research & Enterprise ServicesGround Floor, Jenner Wing, St George’s University of London, Cranmer Terrace, Tooting, London SW17 0RE |
| **Sponsored Site Feasibility Checklist Form** |

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| **Part A - Study Details** | |
| Short Study Title: | |
| CI Name: | St George’s JRES Ref: |

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| **Part B – Site Details** | |
| Site Name: | Hospital  GP Practice  Other, please State: |
| Proposed Site Recruitment Target: | Proposed Number of Months study will be active at  this site for (from FPFV to LPLV): |
| **If Site Visit conducted**  **Performed by and Date (dd/mm/yyyy):** | |

| **Part C – Contact Details** | |
| --- | --- |
| Proposed Investigator for this site | Prof/Dr/Mr/Mrs/Ms/Miss |
| PI Site/Hospital name  Full postal address and contact details  (tel, email, PA/Secretary) |  |
| Years of research experience: |  |
| Number of studies as Principal or Chief investigator: |  |
| Point of Contact for this site if not the investigator and Study Role: |  |
| Pharmacy Contact for this site  Name and Contact details:  *(include Telephone number and email)* |  |
| Radiology/MRI/Imagining Contact for the site (if applicable)  Name and Contact details:  *(Include Telephone number and email)* |  |
| Pathology/Microbiology/Lab sciences Contact for the site (if applicable)  Name and Contact details:  *(Include Telephone number and email)* |  |
| Clinical Research Facility (CRF) contact for the site (if applicable)  Name and Contact details:  *(Include Telephone number and email)* |  |
| R&D Contact for this site  Name and Contact details:  *(Include Telephone number and email)* |  |

| **Part D - Feasibility Questions** | | | | |
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| **Part D.1 - Investigator** | **Yes** | **No** | **N/A** | **Details** |
| Professional Registration number & Year of Registration |  |  |  |  |
| Have you had GCP training within the last 3 years? (IMP/Regulated Device Trials) |  |  |  |  |
| Previous experience in Clinical Research Studies? |  |  |  |  |
| Does the study team have previous experience of running this type of trial?  **If not,** what training do they require? |  |  |  |  |
| Is there a back-up co-investigator?  This person must be appropriately qualified to sign SAE forms in the absence of the Cl/PI and must be delegated appropriately on the Delegation Log. |  |  |  |  |
| Who will be taking consent?  Are they appropriately qualified to take consent?  Has consent training been delivered? (where appropriate) |  |  |  |  |
| Do you have adequate time and resources to conduct this study? |  |  |  |  |
| Which of the following facilities does your site have for trial use? E.g  - Patient/research area  - WIFI  - Locked drug storage (applicable in CTIMPs trials) |  |  |  |  |
| Are there other competing studies running at your site? |  |  |  |  |
| How many studies are you working on at your site? |  |  |  |  |
| Other support departments:  Which support departments will be required to conduct the study? |  |  |  |  |
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| **Part D.2 – Trial Procedures** | **Yes** | **No** | **N/A** | **Details** |
| Do you foresee any challenges with the use of central labs? |  |  |  |  |
| Are there any challenges with processing samples as described in the protocol (if not already addressed)? |  |  |  |  |
| Where would the samples be processed and by whom? |  |  |  |  |
| Which of the following equipment does your site have for trial use?  E.g  - Blood pressure machine ECG  - Freezer (-80C / -20C)  - Fridge  - Calibrated Centrifuge  - Temperature Monitoring  - Water bath  - Dry Ice for samples shipment  Any study related equipment not listed here are included in the protocol. |  |  |  |  |
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| **Part D.3 - Recruitment** | **Yes** | **No** | **N/A** | **Details** |
| --- | --- | --- | --- | --- |
| Were previous recruitment targets met for other similar studies?  **If not,** what reasons were there and what actions can be taken to avoid in this study |  |  |  |  |
| Does the protocol recruitment strategy fit with your sites Patient Pathway? |  |  |  |  |
| Who will be responsible for driving recruitment at the site?  **If not,** what reasons were there and what actions can be taken to avoid in this study |  |  |  |  |
| Who will be responsible for reporting recruitment at the site?  *(if different to above)* |  |  |  |  |
| Do you foresee any potential problems with recruitment at your site? |  |  |  |  |
| Can you meet the recruitment timelines and targets? |  |  |  |  |
| Are there any seasonal issues that may affect recruitment at your site? |  |  |  |  |

| **Part D.4 – Site Staff** | **Yes** | **No** | **N/A** | **Details** |
| --- | --- | --- | --- | --- |
| Do you have a study coordinator for this study? |  |  |  |  |
| Do you have a study nurse/ healthcare professional for this study? |  |  |  |  |
| Will you be using a bespoke research facility (CRF)?  **If yes**, please provide information on CRF review process and include contact details in Part C: |  |  |  |  |
| Would any of the following make it difficult to identify, recruit or retain suitable participants?   * Inclusion criteria * Exclusion criteria * Study Visit schedule * Disallowed concomitant medication * Drug formulation/route of administration * Other concerns not listed: |  |  |  |  |

| **Part D.5 – Funding** | **Yes** | **No** | **N/A** | **Details** |
| --- | --- | --- | --- | --- |
| Is the funding provided (if applicable) adequate for you to deliver the research in line with the protocol? |  |  |  |  |
| Will an application be made to the LCRN for support costs (where appropriate)? |  |  |  |  |
| Are there any funding concerns that may impact research delivery onsite, considering target and timelines? |  |  |  |  |
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| ***Please, only complete the bellow section if the study is a CTIMP Trial*** | | | | |
| **Part E – Monitoring** | **Yes** | **No** | **N/A** | **Details** |
| Does your site have the facilities and capacity to accommodate trial monitors? |  |  |  |  |
| Will the clinical notes be in paper for monitor review?  *If your site uses EPR systems, will the monitor have permission to access?*  *(Please detail which EPR system is in use)*  *Is the EPR system validated?* |  |  |  |  |
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| **Part E – IMP** | **Yes** | **No** | **N/A** | **Details** |
| Does your Site have experienced research Pharmacists?  Name and Contact details:  *(Include Telephone number and email)* |  |  |  |  |
| Are there any challenges with storage, preparation and administration of IMP at your site? |  |  |  |  |
| Can your site provide the **Write the IMP NAME**?  *(for cases that the IMP is used by the routine pharmacy)* |  |  |  |  |
| Are there any local requirements that need to be met in relation to IMP management?  (e.g. Fridge with temperature monitoring system) |  |  |  |  |
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| **Form completed by:** | |
| **Name** |  |
| **Date (dd/mm/yyyy)** |  |
| **Signature** |  |

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| **Form reviewed by:** | | |
| **Name** |  | |
| **Date (dd/mm/yyyy)** |  | |
| **Signature** |  | |
| **Result** | Feasible  Potentially Feasible  Not feasible at this time |  |
| **Comments** |  | |