A robust feasibility is an essential part of ensuring study delivery. Please pass this Study Feasibility Assessment (SFA) and a copy of the protocol to the individual(s) who are most appropriate to accurately complete the form.

Appended to this SFA should be the latest version of the protocol and information about any funding allocated to the site. In addition, if the study uses Investigational Medicinal Products, a pharmacy feasibility document should also be attached.

Any queries, please contact the study coordinator or the Head of Research Operations at UHL.

|  |  |  |
| --- | --- | --- |
| **Site Name:**  **Site Reference No:**  (if applicable)  Point of Contact Name:  (if different to PI)  POC Email:  POC Phone No: |  | **PI Name:**  **PI Email Address:**  **PI Phone No:** |
| **Research & Development :**  Contact Name:  Email address:  Phone Number: |  | **Contracts Contacts:**  Contact Name:  Email address:  Phone Number: |
| **Postal Address for Research & Development:** |  | **Registered Address for inclusion in the contract:** |
| **Pharmacy :**  Contact Name:  Email address:  Phone Number: |  | **Radiology :**  Contact Name:  Email address:  Phone Number: |
| **Laboratories :**  Contact Name:  Email address:  Phone Number: |  | **Medical Physics :**  Contact Name:  Email address:  Phone Number: |
| **Recruitment Target for Site:** |  |  |

|  |  |  |
| --- | --- | --- |
| **Feasibility Assessment Line of Questioning** | **Site Response –**  **Please add your comments to the question in the box below.**  **Please answer every question.**  **If Not Applicable please state N/A** | **Site Assessment – please indicate your current feasibility status by answering 1,2 or 3:**  **1 – Feasible**  **2 – Potentially Feasible**  **3 – Not Feasible at this time** |
| Does the organisation have an EDGE Instance? |  |  |
| If YES, Please state the exact name of your organisation as it appears in the EDGE system |  |  |
| Is there anything in the protocol which is non- standard for your organisation? |  |  |
| Is there anything in the protocol that you consider ambiguous and that needs to be explained in greater detail? |  |  |
| Are there any procedures within the protocol that require early or additional support from support departments? |  |  |
| Are there several procedures within narrow timelines required? If so, are your support departments, i.e. Labs / Radiology aware and prepared for this? |  |  |

|  |  |  |
| --- | --- | --- |
| **Funding** |  |  |
| Have funds been allocated to your site? |  |  |
| Are they adequate for you to deliver the research in line with the protocol? |  |  |
| Will an application be made to the CRN for support costs (where appropriate)? |  |  |

|  |  |  |
| --- | --- | --- |
| **Resource** |  |  |
| Person responsible for research activities at this site? i.e. PI / CI / Local Collaborator etc |  |  |
| Who will be working on the study?  Please list names of individuals and their role as it will appear on the Delegation Log. |  |  |
| 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?   * 1. This person must be appropriately qualified to sign SAE forms in the absence of the CI 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 site staff have sufficient resource? |  |  |
| How many studies are currently being run by the department? |  |  |
| Are there any studies competing for the same patient population? |  |  |

|  |  |  |
| --- | --- | --- |
| **Facilities** |  |  |
| Does the site have adequate facilities & equipment to accommodate the study? - Patient/research area - Blood pressure machine  - ECG - Freezer - Fridge - Centrifuge   * - Centrifuge calibration * - Temperature Monitoring   - Water bath  Any study related equipment not listed here but included in the protocol. |  |  |
| If not, how will the site access facilities/equipment? |  |  |

|  |  |  |
| --- | --- | --- |
| Other support departments:  Which support departments will be required to conduct the study?  NB Where pharmacy is required a separate pharmacy feasibility document must be completed. |  |  |

|  |  |  |
| --- | --- | --- |
| **Recruitment** |  |  |
| Were previous recruitment targets met for other similar studies? |  |  |
| Does the protocol recruitment strategy fit with your sites Patient Pathway? |  |  |
| Who will be responsible for driving recruitment at the site? |  |  |
| 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? |  |  |
| What is your current metric on meeting the recruitment targets? (70day target%) |  |  |
| Are there any seasonal issues that may affect recruitment at your site? |  |  |

|  |  |  |
| --- | --- | --- |
| **Governance** |  |  |
| Has everyone got an up-to-date CV and GCP training certificate (where appropriate)? |  |  |
| Who will be responsible for ensuring site file is kept inspection-ready? |  |  |
| Where are files and study related documents stored?  Where will Site Files be archived at the end of the study? |  |  |
| **Comments** |  |  |
|  | | |