**Study Feasibility Assessment (REMOVE THIS PAGE BEFORE SENDING TO SITES)**

Investigators wishing to undertake research that is sponsored by the DMU must contact the Research Governance Officer at the earliest opportunity to discuss the process for site selection. The Sponsor Application and Risk Assessment process includes a requirement that each site selected to host the research has completed a Site Feasibility Assessment (SFA). SFA(s) will be reviewed and discussed as part of the Sponsor Risk Assessment Process. A site without a completed SFA will not receive authorisation to be added as a site from the Sponsor.

The SFA allows sites to make a real time assessment about their feasibility status. There are three options to choose:

• Feasible – no future action required

• Potentially feasible – areas to be addressed / resolved

• Not feasible at this time

It is expected that the Chief Investigator (CI) (or a suitable delegate) will manage the SFA process, and collate all responses from sites to send to the Sponsor. The SFA includes information about all support services within the sites, R&D Offices, contracts contacts and the clinical team. It is expected that an individual within the site be identified to complete the SFA on behalf of the site. This does not necessarily need to be the Principal Investigator (PI) but should be an individual with appropriate organisational knowledge.

It is recognised that there will be sections of the SFA that are not relevant to every study. In these cases, it must be made clear that the protocol does not require these sections to be completed.

When completed, the SFA must be sent to the Research Governance Office for review. The assessment will be discussed with the CI and a decision made about whether or not it is appropriate or feasible for the individual site to be included in the study. This decision will be communicated by letter/email from the Sponsor to the PI, copied to the CI. A copy of the letter/email and the completed SFA must be retained in the site’s Investigator Site File, the CI’s Trial Master File within the individual site section, and the Sponsor file.

There will be an automatic critical finding if it is found that a site has been added to a study without evidence of the SFA process. It is likely that the study will be suspended at all sites while an investigation is carried out.

**Study Feasibility Assessment**

A robust feasibility is an essential part of ensuring study delivery. Please pass this Study Feasibility Assessment 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 your site.

Any queries, please contact the study coordinator or the Research Governance Office.

|  |  |  |
| --- | --- | --- |
| **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** |
| 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 LRN for support costs (where appropriate)? |  |  |

|  |  |  |
| --- | --- | --- |
| **Resource** |  |  |
| 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? |  |  |
| 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** |  |  |