Site Feasibility Assessment (SFA) Form

A robust site feasibility assessment is an essential part of ensuring successful study delivery.

**Instructions to the UoL Research Team:**

1. A SFA must be completed **per site** involved in the delivery of a research study.
2. Please complete Sections 1 and 2 (as well as any other relevant information within the questions) prior to sending the SFA to the potential site.
3. Provide the SFA to the individual(s) at a site who is/are best placed to accurately complete the form.
4. Appended to this SFA should be the latest version of the protocol or study summary and information about any funding allocated to the site.
5. If the study uses Investigational Medicinal Products, a Pharmacy Feasibility Assessment (PFA) should also be attached.
6. The completed SFA should be included with an application for Sponsorship (or amendment, where a site is added via an amendment).
7. Guidance text is provided in blue and should be removed prior to submission of the SFA

**Instructions for the Site undergoing Feasibility Assessment:**

1. Please complete Section 3 onwards.
2. The SFA should be completed prior to your site being named on the IRAS form, or being added as a research site via an amendment.
3. Please complete the SFA accurately and ensure that you obtain the relevant input and sign-off from responsible individuals at your site and in accordance with your local policies.
4. Please add comments/background detail where applicable to help us understand how the study/trial may be implemented at your site.
5. It is important that anything that is atypical or not standard for your site is fully explained (we may be able to amend the protocol to address foreseen issues).
6. Sections and/or statements should be marked as ‘N/A’ where these are not relevant to the site or protocol requirements.
7. Guidance text is provided in blue and should be removed prior to submission of the SFA

# General Study Information and Management (to be completed by the Chief Investigator/Lead Site)

|  |  |
| --- | --- |
| **Study Title/Acronym:** |  |
| **Sponsor reference number:** | xxxx |
| **Chief Investigator:** |  |
| **IRAS number:** |  |
| **Type of study:** | *i.e., whether this is a CTIMP (including the Phase etc)/Non-CTIMP/Interventional study/Randomised/Blinded* |
| **Total recruitment target:** | *Please enter the overall recruitment target for the study* |
| **Is recruitment competitive?** | *Yes/No; provide additional details if required* |
| **Study duration:** | *Start date* |  | *End date* |  |
| **Recruitment period:** |  |
| **Version of the Protocol/Summary:** | *Provided to the site for feasibility assessment* |
| **Funding summary:** | *Please provide an overview of the funding that will be provided to the site including any exclusions and/or expectations about costs that the site needs to cover and payment schedule (i.e., per participant etc)* |
| **Overview of departments and staff required to support the delivery of the study:** | *Please provide an overview of the likely support departments and staff needed at a site for them to effectively deliver the study* |

# Site Information (to be completed by the Chief Investigator/Lead Site)

|  |  |
| --- | --- |
| **Site Name/Number:** | *Please enter the details for the site undergoing feasibility*  |
| **NHS Trust Name:** |  |
| **Proposed site recruitment target:** | *For studies involving multiples arms/sub studies etc please specify the recruitment target per arm/sub-study* |
| **Proposed site start date:** |  |
| **Proposed site recruitment period:** |  |

*The questions below should be adapted to suit the protocol requirements prior to issuing to the site to ensure the information gathered enables a full feasibility assessment.*

# Site Contact Details (to be completed by the site)

|  |  |  |
| --- | --- | --- |
|  | **Name** | **Email** |
| **Principal Investigator (PI):** |  |  |
| **Substantive Employer of PI:** |  | *N/A* |
| **Point of Contact and Role:** |  |  |
| **Lead Nurse:** |  |  |
| **R&D/I:** |  |  |
| **Contract Officer:** |  |  |
| **Laboratory:** |  |  |
| **Radiology:** |  |  |
| **>>insert other contact details as relevant or delete if not applicable<<** |  |

# Site Feasibility Assessment (to be completed by the site)

Based on your review of the available information about the study and the site targets please use the questions below to demonstrate how both the study processes and recruitment target are feasible at your site.

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| --- |
| **1. Study/Trial Population** |
| **Do you have access to the protocol specified patient population?** | [ ]  Yes[ ]  No, please explain how this will be addressed: |  |
| **Will you need to recruit patients from external organisations (i.e., Participant Identification Centres (PICs))?** | [ ]  Yes, please provide details:[ ]  No  |  |
| **Is the proposed recruitment target and period realistic for your site?** | [ ]  Yes, please provide detail to support this decision:[ ]  No, please suggest alternative target/period: |  |
| **Were previous recruitment targets met for similar studies/trials?** | [ ]  Yes[ ]  No, please specify:[ ]  N/A |
| **Do you have any current or potential new studies/trials which may compete against or affect recruitment to this study?** | [ ]  Yes, please provide an overview of the competing studies and an assessment of the impact on recruitment for this study: [ ]  No |
| **Are the inclusion/exclusion criteria overly restrictive?** *i.e., please consider the likely screen failure ratio and the number of screen failures* | [ ]  Yes, please expand:[ ]  No |
| **Do you anticipate any problems recruiting to this study/trial?** | [ ]  Yes, please expand and if able to, suggest how you may be able to overcome these problems:[ ]  No |
| **2. Protocol**  |
| **Is the protocol designed in a way that it can be implemented at your site in accordance with your current processes/patient pathway?** | ☐Yes☐No, please specify how the protocol may need to be altered: |
| **Do you have any other suggestions or modifications for the protocol that you would like to be considered by the CI and Sponsor?** | [ ]  Yes, please specify how the protocol may need to be altered:[ ]  No |
| **3. Procedures and Facilities** |
| **Do you have adequate facilities and equipment to accommodate the study/trial?** * **Patient/research area**
* **Laboratory processing of blood, fresh tissue, and urine samples**
* **-80oC freezer to store samples**
* **ECG**
* **<delete/insert other assessments as appropriate>**
 | [ ]  Yes[ ]  No, please specify how you will obtain or access them: |
| **Can relevant services (e.g., laboratory, radiology) meet the protocol requirements?** | [ ]  Yes[ ]  No, please expand: |
| **Are your local laboratories able to process and store samples as per the requirements of the protocol and the UK Regulations for GCP?** | [ ]  Yes[ ]  No, please expand: |
| **Are you able to support all the requirements of the study/trial?** | [ ]  Yes[ ]  No, please detail any potential problems below and how we could help to solve them: |
| **What additional support or resources do you think your site would need, if any, to successfully participate in this study/trial?**  |  |
| **Please state if there are any assessments in the study protocol(s) that your site will not be able to complete, and specify the reason(s) why.** |  |
| **Are you able to support 24-hour cover for un-blinding/code breaking?** | [ ]  Yes[ ]  No, please explain:[ ]  Study is unblinded |
| **4. Staff** |
| **Does the PI have the relevant study/trial experience?**  | [ ]  Yes, please ensure this is documented on the PI Researcher CV[ ]  No, please detail any support the PI will receive/requires: |
| **Do all staff have the relevant study/trial experience?**  | [ ]  Yes[ ]  No, please expand: |
| **How many co-investigators will be involved at your site?** *(NB: a co-investigator is another physician who will work alongside the PI on the study/trial and take full responsibility in your absence)* |  |
| **Based on the information provided, does your site have the staff required to support the delivery of the study/trial?** | [ ]  Yes[ ]  No, please expand: |
| **Where applicable, will all staff complete the required GCP, consent and study specific training?**  | [ ]  Yes[ ]  No, please specify: |
| **5. General set-up information** |
| **What is the typical set-up time for studies/trials at your site?”** |  |
| **What are your local processes for approving a trial at your site (e.g., are there any groups or committees the trial must be submitted to for approval)?****Please give an estimate timescale for this process at your site.** |  |
| **In which form are your medical records?** | [ ]  Paper[ ]  Electronic[ ]  Both/hybrid, please explain: |
| **If electronic, will access be granted to monitors/auditors?**  | [ ]  Yes[ ]  No, please explain how monitoring/auditing can occur:[ ]  N/A |
| **Can office space be made available for trial monitoring by a member of the coordinating centre/sponsor if/when required?** | [ ]  Yes[ ]  No, please explain how monitoring/auditing can occur: |
| **Does your team/site support remote monitoring (either via online visit or completion of self-assessment)?** | [ ]  Yes, please provide SOP:[ ]  No |
| **Does your team have access to a computer for data entry to the eCRF?** | [ ]  Yes[ ]  No, please explain how data entry can occur: |
| **Do you have archiving facilities for trial documentation for the period specified in the protocol?****<<insert archiving period>>**  | [ ]  Yes, please provide SOP:[ ]  No, please explain how archiving works at your site: |

# Site sign-off (to be completed by a representative from the site and the Chief Investigator/Lead Site/Lead Trial Manager)

|  |  |
| --- | --- |
| **Outcome of feasibility assessment:** | ☐ Feasible – no further action(s) required☐ Potentially feasible – areas to be addressed/resolved☐ Not feasible at this time |
| **Approved by:** | *This should be a representative from the site (i.e., PI or delegate)* |
| **Date:** |  |
| **Reviewed and approved by:** | *This should be the CI/Lead Site delegate* |
| **Date:** |  |