**Site Capability Assessment**

**[*Note: This template should be used as a guide and adjusted to suit the trial in question. All sites participating in a trial must have a fully completed and signed off form. The forms should be filed in the Project Management section of the TMF.]***

A new study **[state title of project]** is in set up and you have been sent this questionnaire as you have previously expressed interest in becoming a participating site. The Chief Investigator / UK Lead Investigator **(delete as appropriate)** for the study **(State name of CI or UK Lead Investigator)** would like to invite you to participate. The purpose of this questionnaire is to confirm your interest and to help us assess the feasibility of conducting this study at your site. Please complete this as accurately as possible and email to **(State name of PM)** at **(Provide email address PM)** by **[state date dd/mm/yyyy].**

If you have any questions about the study or completing this questionnaire, please contact the Project Manager **(state name – Tel number and email address)**.

|  |  |
| --- | --- |
| **Study Title:** | PM to complete |
| **Chief Investigator / UK Lead Investigator:** | PM to complete |
| **Sponsor:** | PM to complete |
| **Planned start date of trial:** | PM to complete |
|  |  |
| **Site Name:** |  |
| **Full postal Address:** |  |
| **Principal Investigator:** |  |
| **Telephone No:** |  |
| **Email address:** |  |

|  |  |
| --- | --- |
| **Local Key Contact Details**  **(e.g. co-investigators, research fellows, Research Nurses, etc)** | |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
|  |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
|  |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

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| --- | --- |
| **Local Pharmacy Contact Details (remove section if not applicable)** | |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
|  |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

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| --- | --- |
| **Local R&I Contact Details** | |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
|  |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

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| **Are you interested in participating in this trial?** | **Yes / No** (*please delete as appropriate*)  If No, ­­please briefly provide your reason:  If you have answered ‘No’, please move straight to the signature section at the end of the form and return as detailed above. | |
|  | | |
|  | | |
| **Recruitment and Capacity**  ***Total recruitment target for the (insert acronym) study is xxx. It is anticipated that each site will be responsible for recruiting xx participants annually, or approx xx per month.*** | | |
| Do you feel your site will be able to recruit to target as detailed in the statement above? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| How many potentially eligible patients does your site see per year? *Please see Clinical Trial Synopsis/Protocol (if available) for eligibility criteria.* | |  |
|  | | |
| What methods will you use to recruit participants? (*e.g. patient database, electronic medical records, referral etc.)* | |  |
|  | | |
| Do you have any current or potential new trials which may compete against or affect recruitment to this trial? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| Are you aware of any national or local guidelines that will impact on the recruitment of this trial? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| Do you have the staff capacity to undertake this trial (e.g. research nurses, data managers, etc.)? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| Do the following supporting department(s) at your site have the capacity to undertake this trial?  **[PM to insert list of supporting department(s) required for the trial]** | | **Yes / No** (*please delete as appropriate)* |
| **Clinical Trial Experience** | | |
| Have you been a Principal Investigator (PI) before? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| Number of trials you have worked on as a PI in the last 12 months? | |  |
|  | | |
| How many of these trials were in this therapeutic area? | |  |
|  | | |
| Have you worked on a trial with [**insert sponsor details**] in the last 12 months? | | **Yes / No** (*please delete as appropriate)* |
|  | | |
| Are you trained in Good Clinical Practice (GCP)? | | **Yes / No** (*please delete as appropriate)*  *Date of training:* |
|  | | |
| Are all site staff who will be participating in the trial at your site, including the pharmacist (if applicable), GCP trained? | | **Yes / No** (*please delete as appropriate)* |

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| **Protocol Specific Assessments** | |
| Does the trial protocol match your standard pathway for this group of patients? | **Yes / No** (*please delete as appropriate)*  *If no, please comment:* |
|  | |
| Can your site comply with the protocol schedule? Please comment on any areas of concern you have. | **Yes / No** (*please delete as appropriate)* |
|  | |
| Will you be able to comply with the follow-up schedule? | **Yes / No** (*please delete as appropriate)* |
|  | |
| Will any trial procedures or study follow-up be performed out with your site? | **Yes / No** (*please delete as appropriate)*  *If yes, please comment:* |

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| **Inclusion/Exclusion Criteria**  **Would any of the following inclusion/exclusion criteria represent any substantial difficulty for recruiting subjects into this study?** | | |
|  | | |
| **Inclusion Criteria** | **Causes difficulties with recruitment?** | **If Yes, please comment:** |
| List here all inclusion criteria. | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
| **Exclusion Criteria** | **Causes difficulties with recruitment?** | **If Yes, please comment:** |
| List here all exclusion criteria. | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |
|  | Yes/No |  |

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| **Study Specific Requirements**  ***Add appropriate details for study specific requirements or delete section if not applicable.***  ***Example questions below - amend and/or delete as appropriate:*** | |
| Do you have the facilities for sample collection and storage at: | (please tick all that apply):  -80oC? □  -20oC? □ |
|  | |
| Do you have the facilities for collection and separation of plasma/serum? | **Yes / No** (*please delete as appropriate)* |
|  | |
| Do you have access to centrifuge for sample processing? | **Yes / No** (*please delete as appropriate)* |
|  | |
| Do you have a suitable resource in place to take the samples for the duration of the trial? | **Yes / No** (*please delete as appropriate)* |
|  | |
| Is your (insert equipment name here) used at your site subject to maintenance and maintenance records/ calibration certificates | **Yes / No** (*please delete as appropriate)* |

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| **General Site Information** | |
| What is the anticipated set-up time for this trial at your site? |  |
|  | |
| Are there any local groups or committees the trial must be submitted to for approval? |  |
|  | |
| The Sponsor may perform pre-arranged site visits for monitoring and audit purposes. Are you able to provide the necessary staff support and access to selected patient notes and trial documents for these site visits? | **Yes / No** (*please delete as appropriate)* |

**Thank you for taking the time to complete this form.**

|  |  |
| --- | --- |
| **Completed by:** |  |
| **Designation:** |  |
| **Date:** |  |

|  |
| --- |
| **\*\*\*Please forward this completed form by email to the Study Project Manager\*\*\*** |
| **[insert name] [insert email address]** |

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| --- |
| **\*Internal – Any Additional Info\*** |
|  |