**Site Selection Report Template**

*This is a template and should be made specific to each study. It is envisaged the Trial coordinator or Trial manager completed this report following a meeting with the site team. It can be changed into a questionnaire format to be completed by the site if the Chief Investigator and team choose to.*

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| **Site Name** |  |
| **Principal Investigator (PI)** |  |
| **Site Type** | *NHS / Non-NHS.* |
| **Site willing to Participate?** |  |
| PI and Site experience | |
| **PI availability** | *Include number of other trials PI is currently running.* |
| **PI experience** | *Specifically discuss the same type/Phase or class of study that is being proposed Clinical Investigations.* |
| **Research team experience** | *Specifically discuss Clinical Investigations.* |
| **List Site team to be allocated to this study** | *Roles can be list in names are to be allocated* |
| **PI and research team trained in Good Clinical Practice (GCP)/ ISO14155 GCP? *Delete as appropriate*** |  |
| **Site staff willing to refresh GCP every 2 years as per Sponsor Policy?** |  |
| **Site Facilities** |  |
| **List relevant Site clinical facilities** | *e.g. Dedicated research clinic, clinic room set aside for research etc.* |
| **List Site technical facilities** | *e.g. site has MRI scanner with availability for research.* |
| **Site can complete all protocol/Clinical Investigational Plan (CIP) procedures?** | Please highlight if any procedures will be outsourced |
| Oversight | |
| **Site able and willing to host monitors, auditors and inspectors?** | *This section should also cover Covid -19 or any other pandemic arrangements. Is remote monitoring possible, what are the sites back up plans* |
| **Do electronic health record systems comply with MHRA position statement?** |  |
| **Has the PI / research team been inspected by the MRHA? If yes, what was the outcome?** |  |
| Recruitment | |
| **Projected Recruitment** | *e.g. 10 participants per year / 30 participants total.* |
| **Patient Population Available?** |  |
| **Any competing trials?** |  |
| **Who will be responsible for recruitment?** |  |
| **Will any other departments be involved in recruitment?** |  |
| **Number of eligible patients seen per month?** |  |
| **Expected screen failure rate?** |  |
| **Will recruitment be ‘seasonal’?** | e.g. will twice as many eligible patients present during the winter months? |
| **Any expected challenges to recruitment?** |  |
| Laboratories | |
| **List Site laboratories to be used and comment on scope to perform tests** | Please highlight if any test will be outsourced |
| **Can the Site perform all Test outlined in the protocol/CIP?** |  |
| **Will site laboratories accreditations cover the required tests?** |  |
| **Do the labs have capacity to process the required tests?** |  |
| **Are facilities available for processing central lab samples prior to shipment?** |  |
| Device specific ( delete if not applicable) | |
| **Adequate storage space to store investigational devices?** |  |
| **Capability to calibrate and maintain investigational devices?** |  |
| **Capability to sterilise investigational devices?** |  |
| **Capability to dispose of used investigational devices?** |  |
| IMP specific ( Delete if not applicable) | |
| **Adequate storage space to store IMP?** |  |
| **Adequate facilities to store IMP?** | Egg freezer, fridge etc |
| **Adequate resourced to conduct all IMP related activities?** |  |
| Site Set up details | |
| **Average time to confirm Capacity and Capability?** |  |
| **Site R&D governance contact** |  |
| **Site R&D costing and contracts contact** |  |
| **Site Clinical Physics Contact** | If a Clinical Investigation |
| **Site Clinical Trials Pharmacist contact** | If CTIMP/ATMP |

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| **Summary** | *Please insert a summary of key positives and any challenges identified.* | | |
| **Does the site meet the Pre-defined criteria for selection?** | *Yes or No*  *Please insert how the site meets each of the criteria:* | | |
| **Site selected** | **YES/NO** | **Site informed date:** |  |
|  | **Name** | **Role** | **Signature and date** |
| **Sign off Author** |  |  |  |
| **Sign off CI** |  |  |  |