**Staff details**

|  |  |
| --- | --- |
| Name of Proposed Principal Investigator:  |  |
| Job title: |  |
| Telephone No: |  |
| Email address: |  |
| Address: |  |

|  |  |
| --- | --- |
| Name of proposed site study coordinator[[1]](#footnote-1): |  |
| Designation: |  |
| Telephone No: |  |
| Fax No: |  |
| Email address: |  |
| Address: |  |

|  |  |
| --- | --- |
| Name of R&D contact: |  |
| Designation: |  |
| Telephone No: |  |
| Fax No: |  |
| Email address: |  |
| Address: |  |

**Site details**

Has the site participated in clinical trials in [insert research topic here]? Yes / No

*If yes, please give trial names:*

|  |  |  |
| --- | --- | --- |
|  |  |  |
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|  |  |  |
|  |  |  |

Are investigators and research staff at the site familiar with conduct of clinical trials according to the principles of Good Clinical Practice and United Kingdom law (SI 1031 of 2004, as amended by SI 1928 of 2006)? Yes / No

Do / will all investigators and research staff at the site who will be involved with the trial have current GCP training?

 Yes / No

Will a dedicated research nurse/trial coordinator be assigned to this study? Yes / No

*If yes, please provide name(s):*

|  |  |
| --- | --- |
|  | Email: |

Can a site screening log be maintained? Yes / No

Who will take patient consent for the trial?

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |
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**Patients and eligibility**

Are there any trials targeting the same patient population which may potentially compete with this trial running at this site, either at present or in the foreseeable future?

 Yes / No

*If yes, please give details below:*

|  |  |
| --- | --- |
| **Trial name** | **Start and end date** |
|  |  |
|  |  |

Considering the study eligibility criteria, any competing trials, and the referral practice, how many patients will this site recruit:

* Per month (on average):
* In total for the duration of the trial:

Who will be responsible for confirming that patient eligibility is accurate?

|  |  |
| --- | --- |
| **Name** | **Position** |
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**Trial procedures**

Are the investigations, required by the trial (if any), available at this site to the standard required by the study protocol?

|  |  |
| --- | --- |
| e.g.CT Scan | Yes/No |
|  |  |
|  |  |
|  |  |
|  |  |

**Data returns**

Does the site have adequate staff resources to ensure timely completion of CRFs? Yes / No

Please confirm that the site has adequate staff resources to ensure timely data entry into the trial data collection software (INSERT Software Name here), and prompt return of data and responses to data queries: Yes / No

Who will be responsible for managing the identification and reporting of any serious adverse events or concerns regarding individual patients or the trial in general?

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |

Will site research staff will be able to assist with monitoring procedures required by the study Sponsor: Yes / No

Can the Investigator Site File and other trial documentation be archived at the site for a minimum of <<number>> years? Yes / No

 *If Yes, please provide the name of the person(s) to be responsible for archiving*

|  |  |
| --- | --- |
|  |  |

**Final confirmation**

I confirm that as Principal Investigator, I have reviewed the study protocol and that I agree with the responses to the above questions.

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **For office use only** |
| Date form assessed: |  |
| Assessed by: |  |
| Decision: |  |
|  |
|  |

1. responsible for obtaining local study approval and ongoing study administration [↑](#footnote-ref-1)