Clinical Capability Statement

DATE ………………………………….

This is to be used in conjunction with the ‘R&D Operational Capability Statement’ to help self-assess a Trust’s readiness for research

Contents

1. Clinical management arrangements
2. Interests, demographics
3. Staff
4. Facilities
5. Governance
6. Other information

1. Clinical management arrangements

Information on key contacts.

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<tr>
<th>Organisation details</th>
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<tr>
<td>Name of organisation</td>
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<tr>
<td>Clinical lead (with responsibility for reporting on R&amp;D to the organisation Board)</td>
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Key contact details e.g. Principle investigators, lead research nurse

Contact 1:

| Role: |  |
| Name: |  |
| Contact number: |  |
| Contact email: |  |

Contact 2:

| Role: |  |
| Name: |  |
| Contact number: |  |
| Contact email: |  |

2. Interests, demographics

Method of research

What method of research are you interested in - pharmaceutical, interventional, questionnaire, observational

Patient population

What kind of population do you serve eg age, ethnicity, numbers of new patients / Follow Ups,

Disease specific clinics

How many number of disease specific clinics per week/month in your area if research interest

Recruitment potential

What is the trust's ability to recruit eg competing studies, target for study per annum

Research awareness

How are staff and patients made aware about the Trust's involvement and approach to healthcare research
3. Staffing

### Clinical research team

Clinical research team numbers, roles, availability (e.g. principle investigator, research nurse, admin support, research pharmacist, 24hr access, flexible working)

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<th>Organisation's name</th>
<th>Details of collaboration / partnership</th>
<th>Contact name</th>
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### Current skills and training

Levels of research experience and training, eg updated GCP

### Training needs

NIHR DeNDRoN offers access to a variety of training to help conduct your research, for example online GCP training. Does your team have any continuous professional development training needs (see separate training needs assessment proforma)?

4. Research facilities

### Accommodation

For example: Monitoring room; access to printer, computer, phone; secure storage facilities for equipment and record-keeping; overnight facilities; patient lounge, refreshments

### Testing equipment

For example: Monitored fridge, freezer (-20, -80), centrifuge facilities; access to CT scanner, ECG, Cerebrospinal fluid testing, PET scan, volumetric MRI, hoist or weighing chair

### Pharmacy

For example: What level of support is there from pharmacy; ability to label up drugs/create placebo medications; storage facilities, drug accountability, prescribing procedures, IMP storage, storage monitoring, temperature logs, check compliance, IMP returns to company, IMP disposal, study unblinding
5. Information Governance

### Documentation

**How can researchers access patient information?**

### Storage

**What arrangements are in place to maintain study documentation e.g. SOPs, storage?**

### Consent

**What is the current process for obtaining consent e.g. is this done by a doctor or research nurse?**

6. Other Information

### Other information (relevant to the capability of the organisation)

**Do you run memory clinics, or movement disorder clinics? Have you publicised any outcomes from research?**

The three levels of readiness for research are:

- **Level 1 - PIC site leading to observational studies; investigator lead.**
- **Level 2 - More complex non-commercial research.**
- **Level 3 - Commercial and complex non-commercial research.**