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**Appendix 2**

**Sponsor Responsibilities Self Declaration**

It is expected that this Declaration is reviewed, updated and approved regularly. This is the responsibility of the Sponsor. It is recommended that this is done annually as a minimum.

The content of the Declaration should be maintained at a level of detail proportionate to the level and complexity of sponsoring activity within a particular organisation. For example, organisations that sponsor lower risk studies may have less detail in the Declaration than organisations with higher activity involving higher risk studies. It is expected that the level of detail is sufficient to provide the necessary levels of assurance of the sponsoring organisation’s assessment regarding the required resources/processes and infrastructure in place to support the type of studies being sponsored.

**Contents**

A: Organisation sponsor management arrangements

B: Sponsor study capabilities

C: Other Information

**A: Organisation sponsor management arrangements**

Information on Key Contacts

|  |
| --- |
| **Organisation Details** |
| Name of organisation |  |
| Lead sponsor status: | 🞏 NHS or Social Care organisation🞏 Commercial organisation🞏 Academic🞏 Local Authority🞏 Other social care provider (including voluntary sector or private organisation)🞏 Other (If other please specify)  |
| **Confirmed Authorised Signatory on behalf of Sponsor (re section D2 IRAS)** |
| **Contact 1:** |  |
| Role: |  |
| Contact number: |  |
| Contact email: |  |
| **Contact 2:** |  |
| Role: |  |
| Contact number: |  |
| Contact email: |  |
| **Contact 3:** |  |
| Role: |  |
| Contact number: |  |
| Contact email: |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| **Additional information on staffing related to sponsorship activities (optional)**  |
| Roles within Team | Whole time equivalent | Comments |
|  |  |  |
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**B: Sponsor study capabilities**

Information on the types of studies that can be supported by the sponsoring organisation to the relevant regulatory standards

|  |  |
| --- | --- |
|  | **Types of studies organisation has capabilities in (please tick applicable)** |
|  | CTIMPs(indicate phases) | Clinical trial of a medical device | Other clinical studies | Human Tissue: Tissue samples studies | Study Administering Questionnaires | Qualitative study | Establishment of a Research Database | Other |
| As sponsoring organisation |  |  |  |  |  |  |  |  |

Information on infrastructure and partnerships in place to support sponsorship of the above study types

|  |
| --- |
| **Support Structures** |
|  |

**C: Other information**

**Information on organisational Sponsor Standard Operating Procedures (SOPs) & Organisational Policies Register: Provide details of all policies and procedures in place regarding sponsorship to include:**

* **Risk Assessment**
* **Management of allegations of fraud & misconduct re sites/subcontractors/staff**
* **Management of serious breaches of protocol**
* **Staff training regarding policies**

|  |
| --- |
| **Standard Operating Procedures/Organisational Policies and Procedures** |
| **SOP/Policy ref number** | **SOP/Policy Title** | **SOP/Policy Details** | **Valid from** | **Valid to** |
|  |  |  |  |  |
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**Systems and processes in place to illustrate how HRA expectations of sponsors [insert link here] are met:**

|  |  |
| --- | --- |
| **Expectation** | **Evidence to provide necessary level of assurance** |
| **Peer Review** |  |
| **Allocation of roles & responsibilities** |  |
| **Monitoring & audit** |  |
| **Risk Assessment** |  |
| **PPI** |  |
| **Training & Suitability of researchers** |  |
| **Dissemination of research findings** |  |
| **Registration of studies** |  |
| **Project Oversight** |  |
| **Training of sponsors** |  |
| **Training of Supervisors (HEI only)** |  |
| **Availability of Supervisors (HEI only)** |  |

**Information on the agreed escalation process to be used when any highlighted sponsorship issues are raised**

|  |
| --- |
| **Escalation process** |
|  |