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| **Research Sponsorship Application for Projects Requiring Approval by NHS Ethics Committee and Involving Research on Human Subjects, their tissues, organs or data, by Staff and/or Students of Loughborough University** |

***The project must not commence until insurance, ethics approval and sponsorship are obtained***

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| **PART A - PLEASE COMPLETE ALL QUESTIONS** | | | | | | | | | | | | | | | | |
| **1.** | Title of Study: | |  | | | | | | | | | | | | | |
|  | Start date: | | (dd/MM/yyyy) | | | | End date: | | (dd/MM/yyyy) | |  | | | | | |
|  | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
|  | **Researcher’s Details** | | | | | | | | | | | | | | |  |
| **2.** | Title: | Mr/Mrs/Miss/Ms/Professor/Dr | | Name: | | |  | | | | | | | | |  |
|  | School: | | | | | |  | | | | | | | | |  |
|  | Department: | | | | | |  | | | | | | | | |  |
|  | Address: | | | | | |  | | | | | | | | |  |
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|  | Tel: |  | | | | | Email |  | | | | | | | |  |
|  |  | | | | | | | | | | | |  | | | |
| **3.** | Are student researchers involved with this project? | | | | | | | | | | | | Yes  No | | |  |
| **4.** | Is the study based solely on questionnaires, or other research **not** involving invasive techniques or medicinal products? | | | | | | | | | | | | Yes  No | | |  |
|  |  | | | | | | | | | | | |  |  | |  |
| **5.** | Please estimate numbers of volunteers participating in the study: | | | | | | | | | | | | Adults | Minors \* | |  |
|  |  | | | | | | | | | Patients | | |  |  | |  |
|  |  | | | | | | | | | Healthy human volunteers | | |  |  | |  |
|  |  | | | | | | | | | \* Minors under 18 years of age | | | | | |  |
|  | Is this a Multi Centre Trial? | | | | | | | | | | | | Yes  No | | |  |
|  | If yes and the trial is to be sponsored by LU or managed by LU, please estimate numbers of volunteers participating in the study overall: | | | | | | | | | | | | | | |  |
|  |  | | | | | | | | | | | | Adults | | Minors |  |
|  |  | | | | | | | | | Patients | | |  | |  |  |
|  |  | | | | | | | | | Healthy human volunteers | | |  | |  |  |
|  |  | | | | | | | | | | | |  | |  |  |
| **6.** | Does the study involve invasive techniques? | | | | | | | | | | | | Yes  No | | |  |
| **7.** | Does the study involve the use of a medicinal product or the testing of a medical device? | | | | | | | | | | | | Yes  No | | |  |
|  | **IF AN INVESTIGATIVE MEDICINAL PRODUCT IS INVOLVED**  Please indicate which phase category the study falls into | | | | | | | | | | | Phase 1, 2, 3, 4 | | | |  |
| **8.** | Who is the Funder? | | | | |  | | | | | | | | | |  |
| **Will any part of this study take place outside the UK?** | | | | | | | | | | | | | Yes  No | | |  |
| **If Yes, in which country(ies)?** | | | | |  | | | | | | | | | | | |

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| **PART B - PLEASE COMPLETE QUESTIONS AS APPLICABLE** | | | | | | | | | | | | |
| **9.** | **For Student projects** | | Student status: UG/PGT/PGR | | | | | | | | |  |
|  | **Supervisor’s Details** | |  | | | | | | | | |  |
|  | Title: | Mr/Mrs/Miss/Ms/Professor/Dr | | Name: | |  | | | | | |  |
|  | School | | | | |  | | | | | |  |
|  | Department | | | | |  | | | | | |  |
|  | Address: | | | | |  | | | | | |  |
|  |  | | | | |  | | | | | |  |
|  |  | | | | |  | | | | | |  |
|  | Tel: |  | | | | Email | |  | | | |  |
|  |  | | | | | | | | | | |  |
| **10.** | **For multi site studies** | | | |  | | | | | | | |
|  | How many sites are involved? | | | | | |  | | | | |  |
|  | Is University the lead site? | | | | | |  | | | | |  |
|  | Are any sites outside the UK? | | | | | |  | | | | |  |
|  | Are contracts/site agreements in place? | | | | | |  | | | | |  |
|  |  | | | | | | | | | | | |
| **11.** | **For studies involving the NHS Patients, staff or resources** | | | | | | | | | | | |
|  | Is the study approved by an NHS Trust R+D office? | | | | | | | | Yes  No  Pending | | | |
|  | Is the study approved by an NHS ethics committee? | | | | | | | | Yes  No  Pending | | | |
| **12.** | **For studies using tissue samples** | | | | | | | | | |  | |
|  | Are the tissue samples accessed via a licensed tissue bank? | | | | | | | | | Yes  No |  | |
|  | Are you seeking ethical approval for your study? | | | | | | | | | Yes  No | | |
| **13.** | **For all studies, will the Applicant be responsible for:** | | | | | | | | | | | |
|  | Reporting amendments to the protocol | | | | | | | | | Yes  No | | |
|  | Reporting adverse events and significant developments | | | | | | | | | Yes  No | | |
|  | If No, who will be responsible? | | | | |  | | | | | | |

**Please send this form with all other supporting documents to:**

**Research Governance Officer**

**Research Office**

**Loughborough University**

**Loughborough**

**Leics LE11 3TU**

**e-mail** [**researchpolicy@lboro.ac.uk**](mailto:researchpolicy@lboro.ac.uk)