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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: |       |  |
|  |  |       |  |
|  |  |       |  |
|  | 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**