**Research Ethics Self-Assessment Form**

| Project Title:  |
| --- |
| Visiting Fellow: |
| Email: |
| Date:  |

**Research involving the National Health Service:**

Does the research involve (delete as applicable):

| a. NHS patients or staff, their tissue/materials or data, or NHS facilities | Yes / No |
| --- | --- |
| b. Social care client? | Yes / No |
| c. A medical intervention or clinical trial outside of the UK? | Yes / No |

If you have answered yes to (a) or (b) above, you require ethics approval from the NHS through the Health Research Authority (HRA) <https://www.hra.nhs.uk/>.

**Research regulated by the Human Tissue Act (2004)**

| Does your research constitute a scheduled purpose under the Human Tissue Act? | Yes / No |
| --- | --- |

**Research involving data**

| Does your project include ‘personal’ data (i.e. data which could identify living individuals)? *See* [*ICO definition of ‘personal data’*](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/) | Yes / No |
| --- | --- |
| Are the data a) Anonymised, b) Pseudonymised or c) Identifiable? (there could be any/all within the research) | A / B / C |
| Is/will the University be a [Data Controller](https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf)? | Yes / No |
| Is/will the University be a [Data Processor](https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf)? | Yes / No |
| Has the need for a Data Protection Impact Assessment been considered, or has a DPIA been completed? (*DPIA – legally required under certain circumstances within GDPR*) <https://www2.le.ac.uk/offices/ias/privacy-impact-assessments>  | Yes / No |
| Is/will data be accessed and held a) at the University of Leicester, b) elsewhere, or c) both? | A / B / C |
| Do you have this data now? If ‘no’, when will the project start or data be generated/received? | Yes / No |
| (If yes) Where is the data stored? a) UK, b) EU/EEA, c) Outside EEA – if so which country? | A / B / C |

**Research involving animals**

| a. Does the research involve the use of animals within the UK, with this research being undertaken under the Animal (Scientific Procedures) Act 1986? | Yes / No |
| --- | --- |
| b. Does the research involve the use of animals which is not regulated by Animal (Scientific Procedures) Act 1986? | Yes / No |
| c. Does the project involve the use of animals outside the UK | Yes / No |

**Other research undertaken at the University**

| a. Will the research involve humans as participants with or without their knowledge or consent at any time? | Yes / No |
| --- | --- |
| b. Will the research expose participants to physical or psychological harm? | Yes / No |
| c. Will the research expose researchers to physical or psychological harm? | Yes / No |
| d. Will you have access to personal information that allows you to identify individuals or to corporate or company confidential information that is not covered by confidentiality terms within an agreement or be a separate confidentiality agreement? | Yes / No |
| e. Does the research present a significant risk to the environment or society? | Yes / No |
| f. Does the research present a significant risk to the reputation *(e.g. substantial adverse press, negative impact on day to day business or loss of external trust)* of the University of Leicester? | Yes / No |
| g. Are there any other ethical issues that may require ethical review? | Yes / No |

If you have answered YES to any of the questions on this page, please consult with your academic host whether you need to apply for Ethics approval.

**Declaration**

In completing and submitting this Research Ethics Self-Assessment form, I declare that I:

* Have answered all the questions truthfully and to the best of my knowledge, and that I take full responsibility for these responses.
* Undertake to observe ethical principles throughout the programme of research and report any changes affecting the ethical issues arising from the project to my School or Institute Research Ethics Committee.
* Agree to abide by the UK Research Integrity Office’s code of practice for research, the University’s research ethics policy and any other policies, procedures or guidance related to research conduct or integrity issued by the University of Leicester.

| **Visiting Fellow signature**: |  |
| --- | --- |
| Name:  |  |
| Date: |  |

| **Academic host signature:** |  |
| --- | --- |
| Name:  |  |
| Date: |  |