

**Application for inclusion of a research study that requires a review by a Health Research Authority (HRA) Research Ethics Committee (REC) and/or HRA approval.**

Please complete this form if your study requires review by a HRA REC and/or HRA approval.

There is no need to complete the ‘Application for inclusion of a research study that requires UCL ethical approval’ form in addition to this one. The ‘Application for inclusion of a research study that requires UCL ethical approval’ form should only be completed if you are seeking approval from the UCL REC.

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| 1. **STUDY DETAILS**
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| A1. | Title of the study: |  |
| a. | Short title of the study: |  |
| b. | Sponsor of the study: |  |
| c. | EDGE number (from Sponsor) |  |
| d. | IRAS project ID (if known): |  |
| 1. **CHIEF INVESTIGATOR (CI)**
 |
| B1. | Full name: |  |
| a. | Address: |  |
| b. | Email: |  |
| c. | Does the CI have a substantive contract of employment with UCL?  |  |
| d. | If not, who is the employer of the CI? |  |
| 1. **EDUCATIONAL PROJECT**
 |
| C1. | Is the study, or any part of it, being undertaken as an educational project? **YES/NO** |  |
| a. | If yes, is the student registered at UCL? **YES/NO** |  |
| b. | If the student is not registered at UCL, where are they registered? |  |
| 1. **STATUS OF UCL**
 |
| D1. | For the processing of this personal data, is UCL a controller, joint controller or a processor? *A controller determines the purposes and means, i.e. the ‘why’ and ‘how’, of processing personal data.* *A “Joint” Controller is where two or more controllers jointly determine the purposes and means of processing.**A processor is responsible for processing personal data on behalf of a controller and only acts on their instructions.***N.B.** Section N covers data controllers and processors in more detail. |

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|  | Insert 🗸  |
| **Sole Controller** |  |
| **Joint Controller**  | *If yes, please complete D2* |
| **Processor** |  |

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| D2  | **Joint Controller**  | Who are the other controllers?Are the roles and responsibilities of the separate controllers defined in any contract? If so, please provide a copy of this contract when you submit this form, if available.  |
| 1. **LEGAL BASIS**
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| Is the lawful basis for processing:* personal data “public task”?\*  **Yes/No**
* special category data “scientific or historical research purposes or statistical purposes”?\*\* **Yes/No**

***Explanatory Notes:***\*The “public task” lawful basis is detailed in Article 6(1)(e) of the GDPR.\*\* Special category data is sensitive data e.g. information about an individual’s race, ethnic origin, politics, religion, trade union membership, genetics, biometrics (where used for ID purposes), health, sex life, or sexual orientation and is detailed in Article 9(2) of the GDPR. To lawfully process special category data, you must identify **both** a lawful basis under Article 6 and a separate condition for processing special category data under Article 9. These do not have to be linked. |
| *If no, please state legal basis and rationale.* |
| 1. **SUMMARY OF THE STUDY**
 |
| *Please provide a lay summary of the study e.g. the lay summary from the IRAS application. If available, please provide a diagram setting out the information flows.*  |
| 1. **CONFIDENTIALITY ADVISORY GROUP (CAG)**
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| G1. | Will the study require an application to CAG? **YES/NO***Required if you intend to access confidential patient information without consent in England and Wales.* |  |
| a. | If yes, please state the CAG application number (if known): |  |
| 1. **PARTICIPANTS**
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| H1. | Will the study enrol the following vulnerable participants? |

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| --- | --- | --- |
|  | **Yes** | **No** |
| Insert 🗸 |
| **Children under 18** |  |  |
| **People lacking capacity** |  |  |

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| 1. **RECRUITMENT TARGET**
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| I1. | How many participants will be enrolled? |

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|  | Insert 🗸 |
| **1 – 20** |  |
| **21 – 100**  |  |
| **101 – 1000** |  |
| **1001 – 5000** |  |
| **Greater than 5000** |  |

 |
| a. | If greater than 5000, please state the target number. |  |
| 1. **DATA COLLECTION**
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| J1. | What type of information will be collected?*If a mixture of types will be collected, select all that are applicable.*  |

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| **Anonymised data** – no personal identifiers with no link between the individual and the data. |  |
| **Pseudonymised personal data** – e.g. key-coded data which includes some (often partial) personal identifiers (e.g. initials and DOB) thus potential for indirect identification of participants from the information in combination with other information.  |  |
| **Fully identifiable personal data** – e.g. data with any of the following; names, addresses, hospital number, and NHS number.  |  |

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| a. | If personal identifiers (including within pseudonymised data) will be collected, please list all.*e.g. initials, DOB, names, addresses, hospital number, and NHS number.* |  |
| b. | Is it intended to include participants who are prisoners or young offenders in the custody of HM Prison Service or supervised by the probation service? **YES/NO** |  |
| c. | Have you completed a Data Protection Impact Assessment (DPIA)?  **YES/NO/PENDING** If yes, please submit the DPIA with this registration form**.**For guidance, and copies of the UCL DPIA forms, [see](https://www.ucl.ac.uk/legal-services/ucl-general-data-protection-regulation-gdpr/guidance-notices-ucl-staff/data-protection-impact.): https://www.ucl.ac.uk/legal-services/ucl-general-data-protection-regulation-gdpr/guidance-notices-ucl-staff/data-protection-impact. |  |
| 1. **DATA STORAGE**
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| K1.  | What type of information will be stored? *If a mixture of types will be collected, select the most identifiable option.*  |

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| **Anonymised data** |  |
| **Pseudonymised personal data** |  |
| **Fully identifiable personal data**  |  |

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|  | Where will the data be stored by UCL?For data storage outside of UCL see section N. |

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|  | Insert 🗸 for all that apply |
| **UCL Data Safe Haven** |  |
| **UCL system, e.g. ‘S’ drive** |  |
| **Trial unit IT system (external to UCL systems)** |  |
| **Hard drive of a portable device** |  |
| **Cloud**Indicate (🗸) where servers are located | Inside EU/EEA:Outside EU/EEA:If Outside EU/EEA, please specify and indicate if any adequacy decision is in place, e.g. Privacy Shield: |
| **Manual files (includes paper) at UCL** |  |
| **Other, please specify** |  |

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| 1. **STUDY MANAGEMENT**
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| L1. | Is the study being managed through any of the UCL trial units? |

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| --- | --- |
|  | Insert 🗸 |
| **CR UK & UCL Cancer Trials Centre** |  |
| **Comprehensive Clinical Trials Unit** |  |
| **MRC Clinical Trials Unit**  |  |
| **PRIMENT Clinical Trials Unit** |  |
| **SITU** |  |
| **Joint Research Office**  |  |
| **Other, please state** |  |

 |
| a. | Is the study being managed through an external Trials Unit or other organisation? If yes, please state.  |  |
| 1. **TRAINING**
 |
| M1. | Please confirm that all UCL staff working on the study have / will complete UCL’s core mandatory information compliance training 🗸**N.B.** If using the UCL Data Safe Haven, the approved training on data security is NHS Digital’s Data Security Awareness Level 1 course. |

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| * Freedom of information
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| * Data protection (GDPR)
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| * Information security
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| 1. **STUDY COLLABORATORS AND DATA PROCESSORS**
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| *In the table, please list all study collaborators / third parties (not NHS/ research sites), including controllers and processors who will be sending / receiving identifiable or pseudonymised personal data for study purposes or their own purposes.**These can include laboratories, contract research organisations, funders, other universities involved in protocol development or in publishing findings from the study.**It is acknowledged that not all study collaborators / third parties and data transfers will be confirmed at this stage and that this information is subject to change.*

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| Name of third party | Status of party **controller** / **processor**  | Location of collaborator **Inside EU/EEA Outside EU/EEA**  | Activity/ purpose e.g. storage, processing, analysis.  | Method of data transfer e.g. UCL Data Safe Haven, AES-*256* encryption with password.  | Data storage e.g. Private company computers/ system, NHS computers/ system, home or other personal computers, cloud.  | Length of data retention e.g. duration of trial and archive for x years. | Contract in place **YES/NO/****Pending**   |
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| 1. **FORM COMPLETED BY**
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| O1. | Name: |  |
| a. | Position held: |  |
| b. | Department:  |  |
| c. | Faculty: |  |
| d. | School: |  |
| e. | Email: |  |
| f. | Telephone:  |  |
| g. | Date of completion: |  |
| 1. **SUPPORTING DOCUMENTATION AND CHECKLIST**
 |
| Indicate if the research requires the following documentation and submit these with this registration form.  Insert a ‘🗸’ if applicable and document is approved, otherwise please supply a draft (if available) and insert a ‘D’ or a ‘N/A’ if not relevant.

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| 1. Data Protection Impact Assessment (DPIA)
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| 1. Participant information sheet(s) (PIS) and Privacy Notice if separate ***Please list all***
 |  |
| 1. Informed consent form(s)  ***Please list all***
 |  |
| 1. Other documentation being used to invite/inform participants about the research ***Please list all***
 |  |
| 1. Data Sharing/Processor agreements ***Please provide***
 |  |
| 1. Local Data Protection Coordinator notified
 |  |
| 1. [Appropriate safeguards](https://www.ucl.ac.uk/legal-services/sites/legal-services/files/guidance_for_researchers_on_appropriate_safeguards_under_gdpr_2016_and_dpa_2018.pdf) guidance read and implemented
 |  |
| 1. Previous research registration number (only relevant if an extension to previous registration)
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Submit this form electronically and send to data-protection@ucl.ac.uk together with the supporting documentation.

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| **Data Protection Registration (Office use only)** |
| UCL Data Protection Registration Number: | Date issued: |
|  |  |

For further information on Data Protection at UCL, visit UCL’s Legal Services [Data Protection Overview webpage](https://www.ucl.ac.uk/legal-services/data-protection-overview) where you will find links to guidance, policies and training.

**External resources:**

* [Information Commissioner’s Office:](https://ico.org.uk/) https://ico.org.uk/
* [MRC Regulatory Support Centre:](https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/) https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/
* [Health Research Authority](https://www.hra.nhs.uk/): https://www.hra.nhs.uk/