# UCL BioResource

# Stage 2 Study Application Form

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| **1. Study name** |
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| **2. Contact details** |
|  | **Principal Investigator** | **Main Study Contact** |
| **Name** |  |  |
| **Phone** |  |  |
| **Email** |  |  |
| **Address** |  |  |
| **3. How would you describe you study?** |
| **Pilot study to support grant application** [ ]  **Fully funded study** [ ]  |
| **4. What funding do you have available for the study?** |
| *Please give detail below* |

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| **5. Do you have ethics and sponsorship approvals for the study?** |
| *Please give details below (please provide REC and JRO reference numbers)*

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|  | **REC reference number** | **JRO reference number** |
| **Yes** [ ]  |  |  |
| **No** [ ]  |  |  |
| **Pending** [ ]  |  |  |

 *Please provide any additional information below* |

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| **6. Study type** |
| *Please define the type of study this will be from the options below* |
| **Recall of volunteers**  |[ ]  **Pre-existing UCL BioResource data only** |[ ]
| **Total number requested:** |  | **Data requested on X volunteers:** |  |

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| **7. Inclusion criteria - recall by GENOTYPE *(if applicable)*** [ ]  ***Not applicable***  |
| *Please list the SNP(s) and genotype details of interest that will inform the recall or data provision* |
| **Variant ID*****(RS number)*** | **Homozygotes only** | **Heterozygotes only** | **Both** | **Non-SNP variants*****(give details)*** |
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| **Genotype groups to be matched? Yes** [ ]  **No** [ ]  |
| *If yes:***By gender**  [ ]  |  **By age**  |  [ ]  | **Other** [ ] (give details)  |
| **Please state any further details regarding how volunteers will be grouped for recall** *e.g. matched on same day. Give details for each group.* |

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| **8. Inclusion criteria - recall by PHENOTYPE *(if applicable - check all that apply)*** [ ]  ***Not applicable*** |
| [ ]  **Age Please specify age of interest………………………………………………………………………………………**[ ]  **Gender Please specify gender of interest…………………………………………………………………………………**[ ]  **Height Please specify height of interest…………………………………………………………………………………**[ ]  **Weight Please specify weight of interest………………………………………………………………………………..**[ ]  **Ethnicity Please specify ethnicity of interest…………………………………………………………………………….**[ ]  **Primary health diagnosis Please specify diagnosis of interest………………………………………………………..** ***(please specify in ICD10 form)***[ ]  **Additional health diagnosis Please specify diagnosis of interest………………………………………………………..** ***(please specify in ICD10 form)***[ ]  **Medication Please specify medication of interest……………………………………………………………………** ***(please specify in BNF form)***[ ]  **Alcohol consumption****Consumption per week:** [ ]  **0-5** [ ]  **6-10** [ ]  **11-15** [ ]  **16-20** [ ]  **21-25** [ ]  **26-30** [ ]  **31+**[ ]  **Smoking****Cigarettes per week:** [ ]  **<5** [ ]  **5-10** [ ]  **11-20** [ ]  **21-30** [ ]  **31-40** [ ]  **>40**[ ] **Other Please specify……………………………………………………………………………………………………………………** |

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| **9. Exclusion criteria *(if applicable)*** [ ]  ***Not applicable***  |
| *If the exclusion criteria has not been identified from above, please give details below* |
| **10. Metabolites of interest *(if applicable)*** [ ]  ***Not applicable*** |
| *Please give details below* |
| **11. Current Knowledge** |
| *Please detail the current knowledge regarding the functional significance of the marker(s) of interest and their likely associations with disease including risk estimates.* |

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| **12. Study summary** |
| *Please provide an overview of the proposed study including the commitment (i.e. time, biological samples) required by each study participant (up to 1 A4 page maximum).* |

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| **13. Scientific justification** |
| *Please give the scientific justification for the proposed study, including relevant statistical support and previous results (1 A4 side maximum).* |

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| **14. Lay Summary** |
| *Please give a plain English summary of your proposed study, including aims of the research, background, methods and how participants will be involved. (1/2 page A4 maximum).*

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| **15. Data required *(if applicable)*** [ ]  ***Not applicable*** |
| 1. *Please detail the pre-existing UCL BioResource data that you require*
2. *Please indicate if any other database will be accessed to complete the study – please list and give status of any necessary approvals*
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| **16. Volunteer recall requirements *(if applicable)*** [ ]  ***Not applicable*** |
| **Under the terms of BioResource ethics approval recall of participants and further blood samples must be undertaken by BioResource staff. Subsequent activity may be undertaken by either BioResource or study staff dependant on preference and steering group approval. Please detail below.** |
| **Total blood volume required per volunteer: ml** *Please give details for each visit*  |
| *If >50ml per volunteer is required please provide clear justification for the amount requested* |
| *Please detail any other clinical interventions required (e.g. blood pressure, height, weight).*  |
| **Maximum number of samples/day:**  | **Maximum number of samples/week:**  |
| **Please indicate any other limitations** |
| **Please outline any payments volunteers will receive and when these will be made** |
| **Research teams are responsible for all study travel expenses. We expect that you offer to** **reimburse expenses for all volunteers in addition to any payment they receive.** |

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| **17. Previous NIHR BioResource studies of relevance** |
| *If the any of the NIHR BioResources has previously supported any of your studies, please detail the name, study number and any applicable results* |
| **18. Study timeline** |
| *Please provide details of the anticipated timeline with anticipated study start & end dates* |
| **19. Signature of Principle Investigator**  |
| *Please send us this form electronically as a Word document*Print name: Signature: Date:  |
| **20. UCL BioResource Decision**  |
| *To be filled in by the UCL BioResource team* This application has been: APPROVED [ ]  DECLINED [ ]   PENDING REQUEST FOR FURTHER INFORMATION [ ] BY STEERING GROUP COMMITTEE [ ]  INTERNAL REVIEW [ ] (*state names of internal reviewers*) Date:  |

**APPENDIX I – Existing UCL BioResource Sample Provision**

The UCL BioResource is intended to support recall of participants (recruited under ‘stage 1’ BioResource registration) by genotype and or/phenotype **DATA** for research studies (stage 2 BioResource). The saliva, blood, plasma and serum samples collected during stage 1 registration are collected for genotyping and other processes (e.g. metabolic profiling) that the UCL BioResource undertakes as part of its funding and responsibilities within NIHR BioResource. UCL BioResource, therefore does not operate as a biobank.

UCL BioResource utilises a HTA licensed BioBank (at UCL RFH campus) to store the samples collected for the BioResource, and under certain circumstances it may be possible to consider the release of its sample material for research.

This would be dependent on a number of factors, including:

* if there is sufficient residual sample material to release given quantities of material requested and sample processing requirements and plans of the BioResource
* Resources involved in providing samples (e.g. staff time and expertise to extract and process for release, consumables/tubes/racking etc.)
* costs of releasing samples
* source of request (e.g. from a researcher who has contributed to stage 1 cohort recruitment)

Please specify sample material sought below:

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| **Type of sample - No/UBRs** | **Quantity sought (uls/mls)** | **Format (plated, 2D barcoded tubes etc.)** |
| **CEP whole bloods** |  |  |
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| **Extracted DNA** |  |  |
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| **Plasma** |  |  |
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| **Serum** |  |  |
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**19. Signature of Principle Investigator**