Study Summary Template

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| 1. **Study name** | | | | **Study number:** |
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| **2. Contact details** | | | |  |
|  | **Main Study Contact** | **Other Study Contact** | | |
| **Name** |  |  | | |
| **Phone** |  |  | | |
| **Email** |  |  | | |
| **Address** |  |  | | |
| **3. Lay summary** | | | | |
| *Please provide a summary of your study in lay terms that we can send to our volunteers. This will also be added to the study portfolio on the CBR website* | | | | |

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| **4. Volunteer requirements** | | | |
| **Gender** | Male only | Female only | Both |
| **Ethnicity** | Caucasian only | Any ethnicity | Other (please specify): |
| **Age Range** | Upper age limit: | Lower age limit: | No age limit |
| **Total number of volunteers required:**  (include details of phenotypic grouping) | | | |
| **Exclusions** *(please be explicit, the information you provide will be used to invite volunteers to the study)* | | | |
| **Health conditions No health exclusions:**  1.  2.  3.  4.  5.  6. | | | |
| **Medication** *(clarify minimum time since medication, if applicable)* **No medication exclusions:**  1.  2.  3.  4.  5.  6. | | | |
| **Other exclusions** *(e.g family history, alcohol, metal implants etc)*  **No other exclusions:**  1.  2.  3.  4.  5.  **Is your laboratory able to accept Category 3 samples? Yes  No** | | | |
| **Comments** *(please provide any other relevant information regarding inclusion/exclusion)* | | | |

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| **5. Recall by genotype** *(if applicable)* | | | | | |
| *Please list the SNP(s) and genotype groups of interest that will inform the recall* | | | | | |
| **rs number** | | **Homozygotes only** | | **Heterozygotes only** | **Both** |
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| **Genotype groups to be matched? Yes**  **No** | | | | | |
| If yes:  **By gender** | | **By age (< 5yrs)** | | **By age (5 – 10yrs)** | **Other**  (give details) |
| **Matched on the day of appointment** | | | | **Matched at the end of study** | |
| **How many volunteers are needed from each group?** *(specify exact numbers and groups)* | | | | | |
| **6. Volunteer recall** | | | | | |
| **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).* | | | | | |
| **Will volunteer participation be conducted at the CBR? Yes  No**  *If ‘no’ please provide further details on where study participation will take place and details of who will be managing appointments i.e. who will receive volunteer contact details for the study team* | | | | | |
| **Please indicate when volunteers can participate** | | | | | |
| **Days** | | | | **Times** | |
| Monday | | | | Before 09:00 | |
| Tuesday | | | | 09:00 – 13:00 | |
| Wednesday | | | | 13:00 – 17:00 | |
| Thursday | | | | Other time requirements: | |
| Friday | | | | **Can samples be received on consecutive days? Y/N** | |
| **Samples per day** | **Min:** | | **Max:** | **Maximum number of days/week:** | |
| **Maximum time between venepuncture and sample collection by researcher:** | | | | **If >1 sample being collected, maximum time between venepuncture for each volunteer:** | |
| *Please detail any other restrictions on sample collection:* | | | | | | |

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| **7. Blood samples required** | | | | | | | | | | | | | | |
| *Please detail the exact blood requirements i.e. number of blood tubes/anticoagulant* | | | | | | | | | | | | | | |
| **Type of Blood Tube** | | | | | | | | **Number of each tube required** | | | | | | |
| **EDTA** | | | |  | | | | 2.6ml  4.9ml  9ml | | | |  | | |
| **CPDA** | | | |  | | | | 5.6ml | | | |  | | |
| **LiHep** | | | |  | | | | 4.9ml (gel/liquid)  7.5ml (gel/liquid)  9ml (beaded) | | | |  | | |
| **Serum** | | | |  | | | | 1.2ml  4.9ml  7.5ml | | | |  | | |
| **Other:** | | | |  | | | |  | | | |  | | |
| **Additional information required on the tubes** *(Blood samples are only labelled with study specific barcodes as standard. Information requested must comply with your study’s ethical approval)* | | | | | | | | | | | | | | |
| Gender |  | | Age | |  | Month/year  of birth | |  | Genotype group |  | Other: | |  | |
| *Consent is taken by the CBR clinical team and forms reside in the CBR offices.*  **Does the study team require proof of consent? Yes**  **No** | | | | | | | | | | | | | | |
| *If yes, provide details of where this should be sent:* | | | | | | | | | | | | | | |
| **8. Study expenses and payments** | | | | | | | | | | | | | | |
| *Please outline any payments volunteers will receive and when these will be made* | | | | | | | | | | | | | | |
| **Researchers 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.** | | | | | | | | | | | | | | |
| *The CBR reimburse volunteers directly and re-charge for the expenses. How will the expenses be paid?* | | | | | | | | | | | | | | |
| Invoice | |  | | | | | NHS R&D Cost Centre | | |  | | | |
| Name: | |  | | | | | Budget holder: | | |  | | | |
| Contact details: | |  | | | | | Contact details: | | |  | | | |
| Invoice address: | |  | | | | | Cost centre number: | | |  | | | |
| Account code: | | |  | | | |
| **9. Study timeline** | | | | | | | | | | | | | |
| *Please provide details of the anticipated timeline with potential study start & end dates* | | | | | | | | | | | | | |

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| **10. Study close down** | | | | |
| **The CBR team will send volunteers thank you letters and**  **post-participation feedback questionnaires** | | | | |
| **The study will be expected to provide a lay summary of findings 5 months after it ends,**  **or every 2 years for ongoing studies. This is something that is important to our volunteers**  **and helps to encourage further study participation** | | | | |
| **11. Documents to be included with this application** | | | | |
| Document: | |  | Version number and date: | |
| Copy of REC approval letter | |  |  | |
| Current approved Protocol | |  |  | |
| Approved Participant Information Sheet(s)\* | |  |  | |
| Approved Consent form(s)\* | |  |  | |
| Other approved participant paperwork\* | |  |  | |
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| *\*Please note that study paperwork will be reviewed by the CBR and may be returned with suggestions for amendments* | | | | |
| *If any of the above documents have not been included please give the reason. Recruitment will not commence until we have received all of the above* | | | | |
| **12. Signature of Researcher** | | | | |
| *Please send us this form electronically as a Word document*  Print name:  Signature (optional):  Date: | | | | |
| **13. Amendments** *(CBR to complete)* | | | | |
| **Date** | **Summary of changes** | | | **Changes made by:** |
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