Study Summary Template

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| 1. **Study name**
 | **Study number:**  |
|  |  |
| **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** |
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
| **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** |  [ ]  | 2.6ml4.9ml9ml |  |
| **CPDA** |  [ ]  | 5.6ml |  |
| **LiHep** |  [ ]  | 4.9ml (gel/liquid)7.5ml (gel/liquid)9ml (beaded) |  |
| **Serum** |  [ ]  | 1.2ml4.9ml7.5ml |  |
| **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\* |[ ]   |
|  |  |
| *\*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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