Study Update Request

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| **1. Study details** | | | | | |  | | |
| **Title:**  **Update number:** | | **\_\_\_\_** | | | | **CBR Study number:** | |  |
|  | **Principal Investigator** | | | | **Main Study Contact** | | | |
| **Name** |  | | | |  | | | |
| **Phone** |  | | | |  | | | |
| **Email** |  | | | |  | | | |
| **Address** |  | | | |  | | | |
| **Original Application** *(CBR to fill in)* | | | | | | | | |
| **Number of volunteers requested** | | |  | **Samples requested** | | | (sample only studies) | |
| **Data requested** | | |  | | | | | |
| **Date study approved by SAB** | | |  | **Date study commenced recruitment** | | |  | |
| **Summary of previous Study Updates** *(CBR to fill in)* | | | | | | | | |
| (to include dates of approval) | | | | | | | | |
| **Summary of Current Approval** *(CBR to fill in)* | | | | | | | | |
| **Total number of volunteers approved** | | | (include relevant groups) | **Total number of samples approved** | | | (sample only studies) | |
| **Total data release approved** | | |  | | | | | |
| **\*\*Current Study Update Requested\*\*** | | | | | | | | |
| **Additional number of volunteers requested** | | | (include relevant groups) | **Additional number of samples requested** | | | (sample only studies) | |
| **Additional data release requested** | | |  | | | | | |
| **Other** | | |  | | | | | |

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| **2. Justification for current request** |
| Please give the scientific justification for your request, including relevant power calculations and previous results. |

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| **3. Documentation** | | | |
| **Document type** | **Version & date** | **Document type** | **Version and date** |
| Protocol |  | Ethical approval letter |  |
| Participant Info Leaflet |  | Consent form |  |
| This is the most recent paperwork that we have received from you.  Have any of the above been replaced by more recent versions? YES / NO  If ‘yes’ please list them below and attach copies to this request along with the relevant confirmation of ethical approval: | | | |
| **4. Publication details** | | | |
| Any publications that use Cambridge BioResource volunteer samples or data should acknowledge us with the following wording:  *“We gratefully acknowledge the participation of all NIHR BioResource Centre Cambridge volunteers, and thank the NIHR BioResource Centre Cambridge and staff for their contribution. We thank the National Institute for Health Research and NHS Blood and Transplant. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health & Social Care”* | | | |
| Please give details of **all** current publications resulting from this study that acknowledge the CBR:  **Please ensure the CBR are kept up-to-date with all future publications resulting from this study** | | | |

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| **5. Research data** |
| Any research data generated from the study that will enrich our database and better help the selection of volunteers for future studies should be fed back to us.  Do you have any current data to this effect that we need to be made aware of? YES / NO  If ‘yes’ please give details:  **Please ensure the CBR are kept up-to-date with all future data resulting from this study** |
| **6. Interim analysis** |
| Do you have any interim analysis period planned where you would not wish to receive further samples from the CBR? YES / NO  If ‘yes’ please give details of the time period: |
| **7. Comments** |
| Please let us know if there is anything else we should be aware of: |
| **8. Signature of requestor** |
| Please send us this form electronically as a Word document.  Print name: …………………………………………………  Signature: ……………………………………………………  Date: …………………………. |
| **9. Cambridge BioResource Decision** |
| *To be filled in by the CBR team*  This update request has been APPROVED / DECLINED by SAB / INTERNAL REVIEW (*state who by*)  Date: ………………………………………….. |