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| Loughborough University | **Document Change Note** |
| **The Centre for Biological Engineering** |
| Document Ref: HTA-QS-FORM/003 | Version No: | 1.0 | Issue Date: |  |
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| **DCN No: CBE-HTA/DCN/00011** |  |

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| **Document Reference(s):** | **Document Title:** | **Current****Version No:1.0** |
| **HTA-MI-SOP009**  | Self Inspection Audit for HTA activities  |
| **Reason for** **and overview of the change requested:** | Two new SOPs have been written to support the use of human material from human participants for research. These SOPs cover the fundamental principle of HTA, consent.These new SOPs are:HTA-PR-0012 Obtaining Informed Consent from Human ParticipantsHTA-PR-0013 Withdrawal of consent for using human material for research As part of the CBE audit schedule Consent will now be added to the audit programme. In addition there will be consent taking observations. |
| **Revision Category:** |[x]  All personnel performing this procedure/process must read this version & complete the necessary training |
|  |[ ]  All personnel performing this procedure/process must read this version |
|  |[ ]  No significant changes to document content – no requirement for personnel performing this procedure/process to read this version or complete training |
| **Systems effected by change:** | Amendments to relevant documentation.  | **Other Changes required to implement:** | New Consent audit form – HTA-PR-FORM-0014 has been created for observing consent taking and consent audits. |
| **Date:****27th April 2021** | **Raised by: C.Kavanagh**  | **Date:****22/06/2021** | **Approved by :** **R. Thomas ( Person Designate)****K. Coopman ( Designated Individual)** |