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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/00010** |  | | | |

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| **Document Reference(s):** | **Document Title:** | | | | **Current**  **Version No:1.0** |
| **HTA-RM-SOP003** | Training for HTA Compliance | | | | |
| **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 Participants  HTA-PR-0013 Withdrawal of consent for using human material for research | | | | |
| **Revision Category:** |  | All personnel performing this procedure/process must read this version & complete the necessary training | | | |
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|  | 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:** | Anyone wanting to use human material from human participants will need to do the consent training and read these SOPS.  All other relevant documentation will be amended to reflect the changes. | | **Other Changes required to implement:** | These new SOPS will need to be approved by the PD and DI. Hard copies will be placed in the hard copy file and on the CBE LEARN page. They will be reviewed every 2 years.  All CBE HTA users will be notified of the new SOPS. | |
| **Date:**  **27th April 2021** | **Raised by: C.Kavanagh** | | **Date:**  **22/06/2021** | **Approved by :**  **R. Thomas ( Person Designate)**    **K. Coopman ( Designated Individual)** | |