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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/0009** |  | | | |

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| **Document Reference(s):** | **Document Title:** | | | | **Current**  **Version No:1.0** |
| **QS-Man-001** | Quality Manual | | | | |
| **Reason for**  **and overview of the change requested:** | New project wishes to use human blood from human participants. The quality manual needed to be updated to reflect this change as previously samples were bought from commercial suppliers or tissue banks.  The amendment in the quality manual is:  ‘ It may also acquire human tissue directly from donors or patients in the UK adhering to strict consent procedures.’ | | | | |
| **Revision Category:** |  | 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:** | All relevant documentation will be amended to reflect changes.  All personnel using human participants must complete necessary consent training. | | **Other Changes required to implement:** | All relevant documentation will be amended to reflect changes.  All personnel using human participants must complete necessary consent training. | |
| **Date:**  **27th April 2021** | **Raised by: C.Kavanagh** | | **Date:**  **22/06/2021** | **Approved by :**  **R. Thomas ( Person Designate)**    **K. Coopman ( Designated Individual)** | |