| Loughborough University **The Centre for Biological Engineering** | **Adverse Event Report** | | |
|---|---|---|---|
| Document Ref: HTA-MI-FORM/008 | Version N°: | 1.0 | Issue Date: |

**AER No: CBE-HTA/AER/000**  CAPA No (as applicable): CBE/CAPA/000

| | |
|---|---|
| **Department/School/Centre** | |
| **Name of Person completing this report** | |
| **Adverse Event (AE) Details** | |
| **Date, time of AE observed or occurring** | |
| **Person reporting AE** | |
| **Person AE reported to:** | |
| **Location of adverse event (eg facility, room, area freezer etc)** | |
| **Description of adverse event** | |
| **Previous occurrence** | Have similar adverse events happened before? ☐ Yes ☐ No |
| **Impact of the of the adverse event** *Please tick* | ☐Breach of ethical standards ☐Loss or damage to Relevant Material ☐Loss or damage to data. ☐Breach of data protection/confidentiality ☐Other compliance breaches. *Please state below:* |
| **Severity Category** *Please tick* | ☐ Critical  ☐ Major  ☐ Moderate  ☐ Minor  ☐ Low  **DI Notification required?** ☐Yes ☐No |
| **Was any immediate remedial action performed? List and provide details of action taken** | |
| **List long-term corrective actions, including dates for completion** | |

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| **List preventative actions to be implemented, including dates for completion** | |

| Risk assessment | | |
|---|---|---|
| **Risk Level** *(please tick)* | **Before CAPA** | **After CAPA** |
| Severity of harm to sample | 1 ☐ 4 ☐ 9 ☐ 16 ☐ 25 ☐ | 1 ☐ 4 ☐ 9 ☐ 16 ☐ 25 ☐ |
| Probability of Re-occurrence | 1 ☐ 3 ☐ 5 ☐ 7 ☐ 9 ☐ | 1 ☐ 3 ☐ 5 ☐ 7 ☐ 9 ☐ |
| Likelihood of Detection | 1 ☐ 3 ☐ 5 ☐ 7 ☐ 9 ☐ | 1 ☐ 3 ☐ 5 ☐ 7 ☐ 9 ☐ |
| RPN (indicate risk of re-occurrence)<br>☐ 1-400 (Low Risk)<br>☐ 400-720 (Medium Risk)<br>☐ >720 (High Risk) | ☐ Low  ☐ Medium  ☐ High | ☐ Low  ☐ Medium  ☐ High |
| | | |

| Local Approval* | | |
|---|---|---|
| **Individual name** *(please print)* | **Role** | **Signature & Date** |
| | Person completing the form | |
| | Departmental Person Designate | |
| | Departmental Quality Manager | |
| *Other signatories may be applied, as applicable.  Rows should be added as appropriate.* | | |

| Loughborough University Approval (as required) | | |
|---|---|---|
| **Individual name** *(please print)* | **Role** | **Signature & Date** |
| | | |
| | | |
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**Please retain a copy of this form and forward the original to the Designated Individual as required**