

**School of Life Science**  
**Risk Assessment – HTA**  
**Incorrect Procurement of Human Tissue**

|                       |            |
|-----------------------|------------|
| <b>RA Reference:</b>  | RA/HTA/003 |
| <b>Version Number</b> | 1.0        |
| <b>Date:</b>          | 24/05/2018 |
| <b>Review by:</b>     | 30/05/2020 |

|   |   |                           |
|---|---|---------------------------|
| <b>Author:</b> Dr Robert Fowler<br><b>Designation:</b> Persons Designate – School of Life Sciences                                    | <b>Signature</b><br> | <b>Date</b><br>24/05/2018 |
| <b>Authorised By:</b> Dr Georgios Giamas<br><b>Designation:</b> Designated Individual<br>School of Life Sciences HTA Research Licence |                     | 24/05/2018                |
| <b>Expert Authorisation</b><br><b>Designation:</b><br><b>Contact Details</b>  |   |                           |

| Version | Date | Reason for Change |
|---------|------|-------------------|
|         |      |                   |

**Risks should be evaluated using the following system, assessing the Likelihood (L) of the risk and the Severity (S) of the risk if it was to occur:**

|                           |          |                |                         |                          |                                |                                  |                                    |
|---------------------------|----------|----------------|-------------------------|--------------------------|--------------------------------|----------------------------------|------------------------------------|
| <b>Likelihood of risk</b> | <b>5</b> | Almost Certain | <b>5</b>                | <b>10</b>                | <b>15</b>                      | <b>20</b>                        | <b>25</b>                          |
|                           | <b>4</b> | Very Likely    | <b>4</b>                | <b>8</b>                 | <b>12</b>                      | <b>16</b>                        | <b>20</b>                          |
|                           | <b>3</b> | Likely         | <b>3</b>                | <b>6</b>                 | <b>9</b>                       | <b>12</b>                        | <b>15</b>                          |
|                           | <b>2</b> | Unlikely       | <b>2</b>                | <b>4</b>                 | <b>6</b>                       | <b>8</b>                         | <b>10</b>                          |
|                           | <b>1</b> | Very Unlikely  | <b>1</b>                | <b>2</b>                 | <b>3</b>                       | <b>4</b>                         | <b>5</b>                           |
|                           |          |                | No tissue damage/loss   | Minor tissue damage/loss | Significant tissue damage/loss | Tissue destroyed but replaceable | Tissue destroyed and irreplaceable |
|                           |          |                | No risk to personnel    | Minor risk to personnel  | Medium risk to personnel       | Significant risk to personnel    | Major risk to personnel            |
|                           |          |                | <b>1</b>                | <b>2</b>                 | <b>3</b>                       | <b>4</b>                         | <b>5</b>                           |
|                           |          |                | <b>Severity of risk</b> |                          |                                |                                  |                                    |

**Score Action to be taken:**

0-5 No further action needed.

6-9 Appropriate additional control measures should be implemented

10-25 Work should not be started or should cease until appropriate, additional, control measures are implemented.

**Reducing risk:** procedural planning, contingency planning, personnel training and re-evaluation of procedures can be considered to reduce risk.

**Section 1 – Storage**

|                        |             |  |
|------------------------|-------------|--|
| SCHOOL : LIFE SCIENCES | GROUP : HTA | TASK / ACTIVITY: Procurement of Human tissue |
|------------------------|-------------|--|

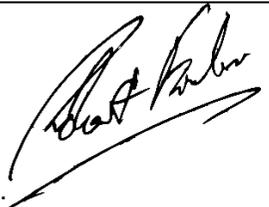
| Section 2 - Identifying Hazards |   | Section 3 - Existing Control Measures  | Section 4 – Evaluating Risk | Section 5 – Action Plan  |                        |   |  |                                |
|---------------------------------|---|--|-----------------------------|--|------------------------|---|--|--------------------------------|
| Hazard                          | Persons/material at risk and how affected                         | Existing Control Measures  | Risk Rating<br>(LxS=R)      | Action required to control risk  | Risk Rating<br>(LxS=R) | Action by Whom  | Deadline for action                                    | Date completed                 |
| <i>Example</i>                  | <i>Type the text in here to describe the hazard</i>               | <i>Describe any existing control measures</i>  | $4 \times 5 = 20$           | <i>Type the text in here to describe the action required to reduce the risk to an acceptable level</i> | $4 \times 1 = 4$       | <i>The name of the person given the action – they must agree to it!</i> | <i>The date by which the action is to be completed</i> | <i>Date actually completed</i> |
| No evidence of consent          | - Donor may have given sample without proper consent being given. | <ul style="list-style-type: none"> <li>- Consent training required by all who take consent</li> <li>- Agreement with institutions that give or sell us material that consent has been obtained following the HTA codes and standards</li> </ul>  | $1 \times 4 = 4$            |  |                        |   |  |                                |
| Insufficient ethical approval   | - Out of date or insufficient ethical approval                    | <ul style="list-style-type: none"> <li>- Requirement to consult with DI prior to commencing any human tissue-related activity</li> <li>- Completion of Project Assessment Form by PI/PD/DI to ensure all appropriate documentation is in place</li> <li>- An internal audit schedule which checks</li> </ul> | $2 \times 1 = 2$            |  |                        |   |  |                                |

|                  |  |   |           |  |  |  |  |  |
|------------------|--|---|-----------|--|--|--|--|--|
|                  |  | documentation of projects   |           |  |  |  |  |  |
| Documents expire | <ul style="list-style-type: none"> <li>- Project runs beyond ethical approval or is risk assessment is out of date</li> <li>- Risks not adequately controlled</li> </ul> | <ul style="list-style-type: none"> <li>- An internal audit schedule which checks documentation of projects</li> </ul> | 2 x 2 = 4 |  |  |  |  |  |
|                  |  |   |           |  |  |  |  |  |

|  |   |
|--|---|
| With monitoring required?  | Yes   |
| Is a more detailed assessment (e.g. Clinical Risk, COSHH, Manual Handling, Display Screen Assessment) required?<br>Please state which one: | No, unless the samples are suspended in something which could be considered a hazardous chemical, then COSHH should be completed. |
| Is further information or investigation required to complete risk assessment?  | No  |

**Section 7 - Assessment Sign Off**

|                                 |                                   |
|---------------------------------|-----------------------------------|
| ASSESSOR'S NAME : ROBERT FOWLER | JOB TITLE : TECHNICAL COORDINATOR |
| DATE OF ASSESSMENT : 24/05/2018 | REASSESSMENT DATE : 30/05/2020    |
|                                 | A                                 |
|                                 | B                                 |
|                                 | C                                 |
|                                 | D                                 |

| ASSESSOR'S SIGNATURE :  | E<br>SAFETY OFFICER'S SIGNATURE : |      |
|--|-----------------------------------|------|
| PERSON INVOLVED NAME   | SIGNATURE                         | DATE |
| <u>Dr Georgios Giamas</u>  |                                   |      |
|  |                                   |      |
|  |                                   |      |
|  |                                   |      |
|  |                                   |      |
|  |                                   |      |