

**For Office Use Only: EHSREC No: \_\_\_\_/\_\_\_\_**

**University of Limerick Research Ethics Committee**

### Risk Assessment Form – Procedures Involving Human Subjects

|  |  |
| --- | --- |
| Procedure No |  |

|  |  |
| --- | --- |
| Title of Procedure |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Assessor(s)** |  | Assessment Date  |  / / |

|  |  |
| --- | --- |
| Does this procedure already have ethical approval? (Delete as appropriate) | YES/NO |

|  |  |
| --- | --- |
| If **YES**, enter ethical number and expiry date | **Approval No:**  |
|  | Expiry Date: / / |

|  |
| --- |
| **1 Please provide a brief description of the procedure** |

|  |
| --- |
| **2 Location in which the procedure may take place** |

|  |  |  |
| --- | --- | --- |
|  |  | e.g. Teaching Laboratory (Room No: ) |
|  |  |  |
|  |  | e.g Research Laboratory (Room No: ) |

 Others, please specify

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| **3 Eligibility of subject(s) to be used** |

|  |  |  |
| --- | --- | --- |
|  |  | e.g. PESS student (U.G. or P.G.) |
|  |  |  |
|  |  | e.g. University staff or campus personnel |
|  |  |  |
|  |  | e.g. Members of the general public engaged in research projects granted ethical approval. |

**For Office Use Only: ULREC No: \_\_\_\_/\_\_\_\_**

|  |
| --- |
| **4 Potential risks. To be explained before obtaining consent** |

|  |  |  |
| --- | --- | --- |
|  |  | None, or minimal discomfort only |

If the risks are other than trivial please provide a brief description.

# For example: In normal, healthy subjects the risks are equivalent to exhaustive exercise of competitive sport.

**Subjects over the age of 35 years MUST obtain the advice of their clinician prior to proceeding.**

The subject should **not participate** in the test if there is a recent history of illness, recurrent injury or medication. These are identified in the pre-test questionnaire.

Please include any other potential embarrassment to the subject which should be explained to the subject by the supervising personnel (e.g. state of undress etc.)

|  |
| --- |
| 5 Action to be taken in the event of an foreseeable emergency |

Please provide a clear statement of appropriate action including contact names and telephone numbers.

# For example: 1. Remove the subject from the ergometer

 2. Check vital signs: airways, breathing and circulation (ABC)

 3. Apply CPR if required

|  |
| --- |
| **6 Level of supervision required for procedure** |

|  |  |  |
| --- | --- | --- |
|  |  | e.g. lecturing/research staff  |
|  |  |  |
|  |  | e.g. postgraduate researcher  |

 Others, please specify

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| 7 Other documentation required for this assessment ? |

|  |  |  |
| --- | --- | --- |
|  |  | Pre-test subject questionnaire |
|  |  |  |
|  |  | Detailed protocol |

 Others, please specify

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

**For Office Use Only: ULREC No: \_\_\_\_/\_\_\_\_**

**FOR COMPLETION BY HEAD OF DEPARTMENT**

###### Risk Assessment Form – Procedures Involving Human Subjects

**In the Department of : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| Procedure No |  |

|  |  |
| --- | --- |
| Title of Procedure |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Assessor(s)** |  | Assessment Date  |  / / |

|  |
| --- |
| **8 Approval of procedure** |

|  |  |  |
| --- | --- | --- |
|  |  | Granted |
|  |  |  |
|  |  | Subject to conditions (see below) |

Others, please specify

|  |  |  |
| --- | --- | --- |
|  |  | Refer to Medical Ethics |
|  |  |  |
|  |  |  |

**Comments/conditions**

Informed consent must be completed.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Head of Department)