Tissue Establishment Annual Report for Reproductive Tissues/Cells

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| Annual report year: |  |

PART A – DETAILS OF TISSUE ESTABLISHMENT

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| Name of tissue establishment |  |
| Full address of tissue establishment |  |
| Authorisation number | **TE-** |

PART B – ACTIVITIES OF TISSUE ESTABLISHMENT DURING THE REPORT YEAR

**Section 1 – Donation/procurement**

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| 1.1  In total, how many oocyte retrievals were performed which resulted in the procurement of oocytes intended for human application? |  |
| 1.2  In total, how many oocytes were procured? |  |
| 1.3  In total, how many of the oocytes procured in 1.2 were donated for non-partner use? |  |
| 1.4  In total, how many units of sperm intended for human application were procured? |  |
| 1.5  How many of the procured units in 1.4 above were collected via surgical sperm retrieval procedures? |  |
| 1.6  How many of the procured units in 1.4 above were collected via electro-ejaculation? |  |
| 1.7  How many procedures were performed which resulted in the procurement of ovarian tissue intended for human application? |  |
| 1.8  How many units of ovarian tissue were procured? |  |

Section 2 – Testing

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| 2.1  Provide the total number of individuals who attended the TE for treatment and who were tested for the following infectious disease markers: HIV 1&2, Hepatitis B, Hepatitis C and Syphilis. | |  |
| 2.2  Provide the number of individuals who were confirmed positive for each of these infectious disease markers: | | HIV 1 and 2:  Hepatitis B:  Hepatitis C:  Syphilis: |
| 2.3  Provide the number of individuals who were confirmed positive for each of these infectious disease markers and who were accepted for treatment: | | HIV 1 and 2:  Hepatitis B:  Hepatitis C:  Syphilis: |
| 2.4  Please provide the name(s) and address(es) of the testing laboratory(ies) which performed the donor testing. | | |
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Section 3 – Cryopreservation of gametes and ovarian tissue

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| 3.1  How many units of sperm were cryopreserved? |  |
| 3.2  How many of the above units were cryopreserved due to oncology indications? |  |
| 3.3  How many oocytes were cryopreserved for partner use? |  |
| 3.4  How many oocytes were cryopreserved for non-partner use? |  |
| 3.5  How many oocytes were cryopreserved due to oncology indications? |  |
| 3.6  How many units of ovarian tissue were cryopreserved? |  |
| 3.7  How many of the above units of ovarian tissue were cryopreserved due to oncology indications? |  |
| 3.8  How many embryos were cryopreserved? |  |

Section 4 – Processing (total numbers)

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| 4.1  What is the total number of units of partner sperm processed? |  |
| 4.2  What is the total number of units of non-partner sperm processed? |  |
| 4.3  What is the total number of units of partner oocytes processed? |  |
| 4.4  What is the total number of units of oocytes processed for non-partner use? |  |
| 4.5  What is the total number of units of embryos processed using:  1: partner sperm and partner oocytes  2: partner sperm and non-partner oocytes  3: non-partner sperm and partner oocytes  4: non-partner sperm and non-partner oocytes | 1:  2:  3:  4: |
| 4.6  What is the total number of units of ovarian tissue processed? |  |

Section 5 – Intrauterine insemination (IUI)/Artificial insemination (AI)

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| 5.1  How many procedures of IUI/AI were carried out with partner sperm at the tissue establishment? |  |
| 5.2  In total, how many units of partner sperm were used in the procedures described above? |  |
| 5.3  How many patients underwent IUI/AI procedures using partner sperm? |  |
| 5.4  How many procedures of IUI/AI procedures were carried out with non-partner sperm at the tissue establishment? |  |
| 5.5  In total, how many units of non-partner sperm were used in the procedures described above? |  |
| 5.6  How many patients underwent IUI/AI procedures using non-partner sperm? |  |

Section 6 – Gamete intrafallopian transfer (GIFT) procedures

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| 6.1  How many gamete intrafallopian transfer (GIFT) procedures were carried out at the tissue establishment? |  |
| 6.2  How many patients underwent gamete intrafallopian transfer (GIFT) procedures? |  |
| 6.3  How many units of the following were used in the procedures described above?  1: Partner sperm  2: Partner oocytes  3: Non-partner sperm  4: Non-partner oocytes | 1:  2:  3:  4: |

Section 7 – Ovarian tissue

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| 7.1  How many units of ovarian tissue were released for human application at the tissue establishment? |  |
| 7.2  How many patients underwent procedures which involved the receipt of ovarian tissue or its by-products? |  |

Section 8 – *In vitro* fertilisation (with or without intracytoplasmic sperm injection)

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| Please complete this section for *in vitro* fertilisation (IVF) procedures, with or without intracytoplasmic sperm injection (ICSI), which were carried out at the tissue establishment. | |
| 8.1  For *in vitro* fertilisation cycles with partner sperm and partner oocytes:   1. How many cycles were started? 2. How many cycles progressed to oocyte collection? 3. How many cycles involved intracytoplasmic sperm injection (ICSI)? 4. How many cycles resulted in fresh embryo transfer? 5. How many embryos were transferred in total? 6. How many patients received embryo transfers? 7. How many cycles resulted in the cryopreservation of embryos/zygotes? | 1:  2:  3:  4:  5:  6:  7: |
| 8.2  For *in vitro* fertilisation cycles with non-partner sperm and partner oocytes:   1. How many cycles were started? 2. How many cycles progressed to oocyte collection? 3. How many cycles involved intracytoplasmic sperm injection (ICSI)? 4. How many cycles resulted in fresh embryo transfer? 5. How many embryos were transferred in total? 6. How many patients received embryo transfers? 7. How many cycles resulted in the cryopreservation of embryos/zygotes? | 1:  2:  3:  4:  5:  6:  7: |
| 8.3  For *in vitro* fertilisation cycles with partner sperm and non-partner oocytes:   1. How many cycles were started? 2. How many cycles progressed to oocyte collection? 3. How many cycles involved intracytoplasmic sperm injection (ICSI)? 4. How many cycles resulted in fresh embryo transfer? 5. How many embryos were transferred in total? 6. How many patients received embryo transfers? 7. How many cycles resulted in the cryopreservation of embryos/zygotes? | 1:  2:  3:  4:  5:  6:  7: |
| 8.4  For *in vitro* fertilisation cycles with non-partner sperm and non-partner oocytes:   1. How many cycles were started? 2. How many cycles progressed to oocyte collection? 3. How many cycles involved intracytoplasmic sperm injection (ICSI)? 4. How many cycles resulted in fresh embryo transfer? 5. How many embryos were transferred in total? 6. How many patients received embryo transfers? 7. How many cycles resulted in the cryopreservation of embryos/zygotes? | 1:  2:  3:  4:  5:  6:  7: |

Section 9 – Frozen embryo transfer (FET) cycles

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| 9.1  How many thaw procedures were carried out of embryos or zygotes? |  |
| 9.2  How many frozen embryo transfer cycles of the above thawed embryos/zygotes resulted in embryo transfer? |  |
| 9.3  How many frozen embryos were transferred in total? |  |
| 9.4  How many patients received frozen embryos? |  |
| 9.5  How many embryo transfer cycles of 9.2 above involved partner sperm and partner oocytes? |  |
| 9.6  How many embryo transfer cycles of 9.2 above involved partner sperm and non-partner oocytes? |  |
| 9.7  How many embryo transfer cycles of 9.2 above involved non-partner sperm and partner oocytes? |  |
| 9.8  How many embryo transfer cycles of 9.2 above involved non-partner sperm and non-partner oocytes? |  |

Section 10 – Distribution/transport of tissues and cells within the EEA

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| 10.1  Please list the type and number of units of tissues/cells which were **accepted** into the tissue establishment, from another tissue establishment within the European Economic Area, and the country from which they were received. | | |
| **Type of tissue/cell:** | **Number of units accepted into the tissue establishment:** | **Country:** |
| 10.2  Please list the type and number of units of tissues/cells which were **distributed** from the tissue establishment, to another tissue establishment within the European Economic Area, and the country to which they were sent. | | |
| **Type of tissue/cell:** | **Number of units distributed:** | **Country:** |

Section 11 – Import/export

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| 11.1  Please list the type and number of units of tissues/cells which were **imported** by the tissue establishment, from an organisation outside the European Economic Area, and the country from which they were received. | | | |
| **Type of tissue/cell:** | **Number of units imported into the tissue establishment:** | | **Country:** |
| 11.2  Please list the type and number of units of tissues/cells which were **exported** by the tissue establishment, to an organisation outside the European Economic Area, and the country to which they were sent. | | | |
| **Type of tissue/cell:** | **Number of units exported from the tissue establishment:** | **Country:** | |

Section 12 – Additional information

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| Please include details of any other relevant information in this section. |
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Part c – Declarations

Section 1 – Only to be completed by tissue establishments authorised for import

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| I declare that the most up-to-date version of the documents detailed in Annex III of Directive 2015/566 are maintained by the tissue establishment and available at the request of the HPRA.   |  |  | | --- | --- | | Signature: | Date: | |  |  | | Print name: | Title/position: | | (To be signed by the person who has completed the annual report.) | | |

Section 2 – To be completed by all tissue establishments

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| To the best of my knowledge and belief, the information provided in this annual report is correct and complete.   |  |  | | --- | --- | | Signature: | Date: | |  |  | | Print name: | Title/position: |   (To be signed by the person who has completed the annual report.)   |  |  | | --- | --- | | Signature: | Date: | |  |  | | Print name: | Title/position: |   (To be signed by the tissue establishment’s Responsible Person.) |

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| Please complete and return annually by **31 March** to:  Compliance Department  Health Products Regulatory Authority  Kevin O’Malley House  Earlsfort Centre  Earlsfort Terrace  Dublin 2  Tel: + 353 1 676 4971  Fax: + 353 1 676 7836  Or email a completed scanned copy to: [compliance@hpra.ie](mailto:compliance@hpra.ie). |