

Guide to Completion of the Tissue Establishment Annual Report for Reproductive Tissues and Cells

Completion due by 31 March annually

1 SCOPE

This guide is issued by the Health Products Regulatory Authority (HPRA) to provide guidance on completion of the tissue establishment annual report for reproductive tissues/cells.

2 INTRODUCTION

Regulation 10 of Statutory Instrument No. 158 of 2006, European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 requires that all tissue establishments submit to the HPRA an annual report on their activities.

There are two types of tissue establishment annual report forms:

- One form which is specifically for completion by tissue establishments which undertake activities relating to reproductive tissues/cells.
- One form which is specifically for completion by all other tissue establishments.

What is the definition of a tissue establishment?

A tissue establishment means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues and cells for human application are undertaken.

Who needs to complete an annual report?

An annual report needs to be completed by all tissue establishments which operated during the year. Please note that the tissue establishment annual report applies to tissues and cells intended for human application only (and does not apply to tissues and cells which are only used for diagnostic or research purposes). The annual report must be signed by the tissue establishment's Responsible Person.

From where can annual report forms be obtained?

The 'Tissue Establishment Annual Report for Reproductive Tissues/Cells' form is available on the HPRA website. If you have any problems downloading this document you may request one via email from compliance@hpra.ie.

Submission of tissue establishment annual reports for reproductive tissues/cells

Completed reports for the year ending 31 December should be submitted to the HPRA in hard copy, or scanned document by email by 31 March, annually. Relevant addresses can be found on the annual report form.

Further guidance

The following are some brief guidance notes on the completion of the tissue establishment annual report for reproductive tissues/cells. If you have any other queries that are not addressed in this guidance note, please email compliance@hpra.ie.

3 NOTES ON THE COMPLETION OF THE ANNUAL REPORT

Part A – Details of tissue establishment

Please enter the TE number which was assigned to the tissue establishment by the HPRA, e.g. TE 001.

Part B – Activities of tissue establishment during the year

Sections 1–3

These sections are self-explanatory.

Section 4

- In relation to number of units processed, please note that this relates to processing of fresh tissues/cells, thawing of frozen tissues/cells, and processing of any tissues/cells received at the tissue establishment from other tissue establishments.
- In addition, please note that a 'unit' should be considered to be any individual package or container, the contents of which will be applied at once (e.g. a straw with one or more embryos, a sample pot containing a procured sperm sample, a vial/straw/other primary container with an aliquot of sperm).

Sections 5–9

These sections are self-explanatory.

Sections 10–11

- The European Economic Area consists of the 27 Member States of the European Union in addition to Iceland, Norway and Liechtenstein.
- Please provide as much information as possible, e.g.

Type of tissue/cell	Number of units accepted into the tissue establishment
Non-partner sperm	4 vials on 8 Sept 20xx 3 vials on 7 Nov 20xx
Type of tissue/cell	Number of units accepted into the tissue establishment
Embryos	4 embryos in 2 straws on 3 Mar 20xx
Partner sperm	3 straws on 7 Dec 20xx

Section 12

Please use this section of the form as necessary to provide any additional information or clarification.

Part C – Declarations

Section 1 should only be completed by tissue establishments authorised by the HPRA for import of reproductive tissues/cells.

Section 2 must be completed by all tissue establishments.

HPRA
1 December 2021