



Guide for completion of the 2010  
Human Application Annual Activity Report

## Overview

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1. An annual activity report needs to be completed by all Tissue Establishments which operated during the year 2009, as a requirement of the 2004/23/EC parent directive article 10 (1), implemented by the Quality and Safety Regulations 2007. Please note that the Annual Activity Report applies to tissues and cells intended for **human application** only.
2. A **Tissue Establishment (TE)** 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. The establishment will be licensed under **The Human Tissue (Quality and Safety for Human Application) Regulations 2007**.
3. For this year's annual activity data collection, a secure online form has been designed to make it quicker and easier for establishments to complete. This document provides some brief guidance notes to help with your submission, split into three sections;
  - getting started
  - step-by-step guide to submission
  - definitions
4. If you have any queries that are not addressed here, please contact Lucy Atwal, Regulation Officer on 020 7211 3448 or email [Lucy.atwal@hta.gov.uk](mailto:Lucy.atwal@hta.gov.uk).

## Getting Started

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5. Before setting out to complete the 2009 annual activity report, we advise that you first read through the guidance contained in this document and prepare all relevant data for submission. It is important that you submit the correct data; once you have submitted your establishment's annual activity report, you will no longer be able to make changes
6. You should be providing data on your Tissue Establishment (TE) and all licensable activities undertaken between 1 January 2009 and 31 December 2009. This year, we are also recording information about the Third Party Agreements that each TE has in place.

7. To access the online form, please copy and paste this link into your internet browser: <https://online.hta.gov.uk/AnnualActivity/>
8. This is a secure reporting system and you will require a username and password to log in. This is the same username and password which you use to access any HTA online system, such as the licence application system or the DI e-learning course.
9. Only DIs will currently have a username and password, although other appropriate individuals can register to submit annual activity data to us. A robust procedure should be in place at each establishment to identify who can report and how.
10. If you have forgotten your username or password, you can request a reminder by following this link:

[www.hta.gov.uk/login.cfm?widCall1=customWidgets.passwordReminder\\_do\\_1](http://www.hta.gov.uk/login.cfm?widCall1=customWidgets.passwordReminder_do_1)

To register for a username and password please follow this link:

[www.hta.gov.uk/register.cfm](http://www.hta.gov.uk/register.cfm)

## **Step-by-step guide**

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### **Step 1 – Establishment information and declaration**

11. After following the link to the online reporting form (page 3 of this document) and logging in, you will first need to complete the following information about your licensed establishment:
  - TE name
  - licence number
  - address
12. You will next need to complete the declaration to confirm that the information you are providing is an accurate picture of your TE's activities.
13. The 'save and continue' button will save your entries and take you to the next annual activity data page. Clicking this button throughout the submission process will ensure that the system remembers the data you have entered should you wish to log out and return to the submission at another time. You can go back to a previous page by clicking on the links at the top of the screen. After going back to a

previous screen you can make changes and save these by clicking the 'save and continue' button.

[Declaration](#) > [Activities](#) > [Third Parties](#) > [Skeletal](#) > [HSC](#) > [Cord Blood](#) > [Ocular](#) > [Cardiovascular](#) > [Skin](#) > [ATMPs/IMPs](#) > [Other](#) > [Review](#)

14. **Please note** you will not be able to change your submission after you have clicked the 'submit' button at the end of the form.

## Step 2 – Activities and tissue types

15. Using the tick boxes in this section, please highlight the licensable activities undertaken by your TE. Please see the 'Definitions' part of this document for more information about the different licensable activities.
16. You should then use the tick boxes to select each tissue and/or cell type relevant to your TE. If you select 'other (general)' you will be given the opportunity to specify the tissue or cell type when you are entering the quantities on the Quantity data page.
17. **Please note** that we would also like you to indicate if you are procuring tissues or cells for **Advanced Therapy Medicinal Products (ATMPs)** or **Investigational Medicinal Products (IMPs)**.

## Step 3 – Third Party Agreements

18. In this section, please fill in the details of organisations or individuals with whom your TE has a Third Party Agreement. Use the 'add a TPA' button to add extra rows to the table if needed.
19. **Please note**, we are only recording information about Third Party Agreements in respect of **licensable activities** (procurement, testing, processing, storage, distribution and import/export).

## Step 4 – Annual activity data by tissue/cell type

20. The online form will automatically direct you only to the relevant quantity data pages based on the tissue and/or cell types ticked as 'Yes' in Step 2. More information on what we consider one unit for different types of tissues and cells can be found in the 'Definitions' section of this document.
21. Data for each tissue and cell type are collected on separate pages for each of the following groups of tissue:
  - **skeletal tissue** – Bone, tendons/ligaments, cartilage, meniscus, demineralised bone, acellular bone chips

- **haematopoietic stem cells (HSC)** – bone marrow, PBSC, cord blood, donor lymphocyte infusions
- **ocular tissue** – cornea, sclera, ocular limbal stem cells
- **cardiovascular tissue** – heart valves, arterial vessels
- **skin**
- **tissues or cells procured for ATMPs or IMPs**
- **other tissues or cells** – pancreatic islets, hepatocytes, amniotic membrane, other (general)

22. The 'add tissue type' button can be used on the 'other tissues or cells' page to add more 'Other' columns to the data table as needed. Please remember to specify which tissue or cell type you are adding into each 'other' column.

23. The 'save and continue' button will save your entries and take you to the next annual activity data page, until you have completed all of the pages relevant to your establishment.

24. More information on what we consider one unit of different tissues and/or cells to be can be found in the 'Definitions' section of this document.

## Step 5 – Review and submit data to the HTA

25. When you have completed all the relevant sections, the final page of the online form will give you the opportunity to see a full list of the information that you have entered. You can return to any of the previous pages and make changes by clicking on the links at the top of the screen.

26. Using the 'print this page' link will allow you to print a copy of the data on this page for your own records.

27. Once you are satisfied with the information, you will need to click the button to 'submit responses to the HTA'. **Please note**, if you do not press this button then the system will not register your submission and we will not receive your annual activity data.

## Definitions

### General

**Tissue Establishment (TE)** – 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. The establishment will be licensed under The Human Tissue (Quality and Safety for Human Application) Regulations 2007.

**Total number of recipients** –the number of individual patients who received at least one unit of tissues or cells as treatment. This applies to establishments which are directly supplying to end users or are end users themselves. The HTA's traceability standards mean that it must be possible to track every unit of tissues and cells from donor to recipient.

## **Definition of activities**

**Donation** – includes autologous donations as well as allogeneic donation. However, tissues and cells used as an autologous graft (removed and transplanted back to the same individual) within the same surgical procedure and without being subjected to any banking process, are excluded from the Tissue and Cells Legislation, and are not applicable to the Tissue Establishment Annual Report.

**Testing** – in the annual activity report, "Units Tested" refers to units of tissues/cells for which blood testing has been performed to establish the serological status of the donor (including autologous donors).

**Processing** – includes all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications but does not include the processing of test results. All processed units should be included in this number, even if they are not distributed. The units for processing should be considered to be the same as those of the finished product.

**Distribution** – transportation and delivery of tissues or cells intended for human applications (within the European Economic Area). This means the total number of tissues or cells of each type transported to a clinical unit, even if the clinical unit is in the same building or the same floor. If tissues and cells are returned to the tissue establishment without use, they should

be counted only when subsequently redistributed.

**Import/export** – applies only to countries outside the European Economic Area (EEA). The EEA consists of the 27 Member States of the European Union in addition to Iceland, Norway and Liechtenstein.

### **Definition of units for different types of tissues and cells**

- **skeletal tissues** – One unit is one individually packaged graft (e.g. one femoral head, one unit of demineralised bone, one container of bone chips, one femoral strut, one individually packaged tendon or part of a tendon)
- **HSC** – One unit is one single bag or container of cells
- **ocular tissues** – One unit is one individually packaged or contained graft (e.g. one cornea, one piece of sclera)
- **cardiovascular tissue** – One unit is one individually packaged graft (e.g. one valve, one package containing one or more lengths of vessel)
- **skin** – One unit is one container of tissue regardless of the area of skin it contains. If skin is procured at your establishment, please enter the amount of skin collected (in cm<sup>2</sup>) into the second column as well as the number of units
- **amniotic membrane** - One unit is one container of tissue, regardless of the area of tissue it contains
- **tissue or cells procured for ATMPs or IMPs** – The procurement and testing of tissues and cells for use as a starting material in ATMPs or investigational ATMPs falls under the remit of the HTA. For a definition of the different types of ATMPs please refer to the ATMP (Advanced Therapy Medicinal Products) Regulation 1394/2007/EC.