

## **Guide to reporting SAEARs using the Human Tissue Authority Portal**

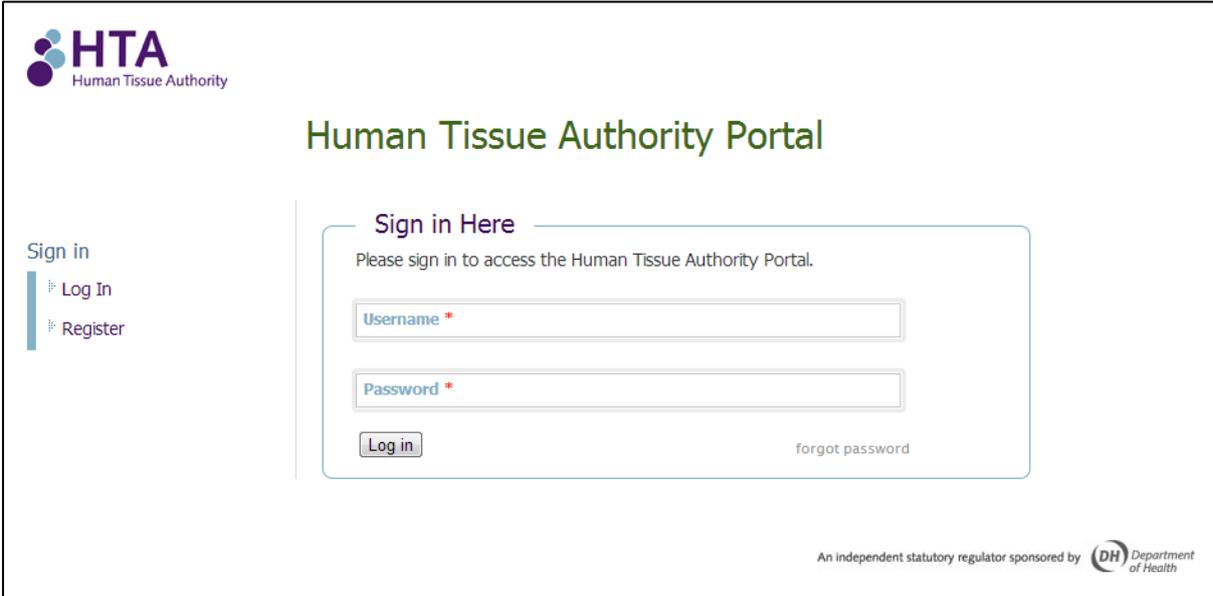
### **About the Portal**

The Human Tissue Authority Portal will allow authorised users to securely view (and eventually manage) licence details and to report serious adverse events and reactions. The Portal is a work in progress and new features and forms will continue to be added.

### **Logging in to the Portal**

You can access the Portal at the following web address: <https://portal.hta.gov.uk/>

This is the welcome screen:



The screenshot shows the Human Tissue Authority Portal login page. At the top left is the HTA logo (Human Tissue Authority). The main heading is 'Human Tissue Authority Portal'. Below this is a 'Sign in Here' section with the instruction 'Please sign in to access the Human Tissue Authority Portal.' There are two input fields: 'Username \*' and 'Password \*'. Below the password field is a 'Log in' button and a 'forgot password' link. On the left side, there is a 'Sign in' section with links for 'Log In' and 'Register'. At the bottom right, it states 'An independent statutory regulator sponsored by DH Department of Health'.

If you are a Designated Individual who has previously logged into the HTA system to report a serious adverse event or reaction in the past, then your user account will have been migrated to the portal.

Your username will be the email address you originally registered with and your password will be the same one you used to login to the previous system.

You are advised to test your access to the Portal as soon as you can to prevent any delays should you need to report a serious adverse event or reaction outside of the HTA's office hours.

You are also advised to change your password after you have logged into the Portal. See Managing your user account below for details on how to change your password.

If you have forgotten your password you can reset your password by using the 'Forgot password' link.

## Registering a new account

If you have never logged into the HTA system to report a serious event or reaction before, you will need to register as a new user.

Registration is simple but your account will need to be verified by a member of the licensing admin team. This will only take place during the HTA's office hours, which are Monday to Friday 9am to 5pm. You should register as soon as possible to ensure there are no delays if you need to report a serious adverse event or reaction outside of these hours.

Click on 'Register' on the left hand side of the welcome screen to register a new account:

### Register New Account

To register for an account on the Human Tissue Authority Portal, please fill in the registration form below.

Your Details

First Name \*

Last Name \*

Username \*

E-mail address \*

Telephone Number

Name of Establishment

Create new account

## Managing your user account

Once you have logged into the HTA Portal you will be taken to the home page which, along with some guidance, lists the user details we have registered against your account. You can get to this page at any time by clicking on the HTA logo or by clicking 'home'.

**Self Service**

- ↳ Licence applications
- ↳ Quality and safety (organs) regulations application
- ↳ **Licence #30108**
- ↳ Reporting
  - ↳ SAR Report
  - ↳ SAE Report

## Jiros

[View](#) [Edit](#)

Welcome to the HTA portal. The details we currently have registered for you are listed below. If you would like to amend these please click 'Edit'.

The 'Self Service' menu on the left hand side of the screen allows you to access any information or forms you are currently authorised to view. You will also be able to view previous submissions of each form.

**Independent and Accredited Assessors** may submit reports using the options listed under 'Transplant and Living Donation'.

**Designated Individuals** will be able to view licence specific information and submit a serious adverse event or reaction for any related licences. To submit a serious adverse event or reaction please select the relevant licence number and then select 'SAE Report' to submit a serious adverse event or 'SAR Report' to submit a serious adverse reaction.

Follow up reports are accessible from the 'Previous Submissions' page for SAEARS reports.

New licence application forms are available to all portal users and can be found under 'Licence Applications'.

If you have any problems please contact us on 020 7269 1900 or [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)

**First Name:**  
Jamie

**Last Name:**  
Munro

**Name of Establishment:**  
HTA

**History**  
**Member for**  
1 month 6 days

To change your password, or to amend any of your user account details click on 'Edit'. In order to change your password you will need to provide your current password.

**YOUR DETAILS**

**First Name \***

**Last Name \***

**Username \***  
  
Spaces are allowed; punctuation is not allowed except for periods, hyphens, apostrophes, and underscores.

**Current password**

Enter your current password to change the *E-mail address* or *Password*. [Request new password](#).

**E-mail address \***  
  
A valid e-mail address. All e-mails from the system will be sent to this address. The e-mail address is not made public and will only be used if you wish to receive a new password or wish to receive certain news or notifications by e-mail.

**Password**  
 Password strength:

**Confirm password**

To change the current user password, enter the new password in both fields.

**Status**  
 Blocked  
 Active

**Telephone Number**

## Your licence information

You will be able to review the details we hold for any licences which you are authorised to view. Licence numbers can be found in the Self Service menu and by clicking on the number itself you will be able to see details we hold about the licensed premises, the Designated Individual, Persons Designated and any Satellite Sites. Eventually DIs will be able to request changes to this information through the Portal but for now you will need to follow the existing process for varying information on a licence.

The screenshot displays the Human Tissue Authority (HTA) Portal interface. At the top left is the HTA logo with the text 'Human Tissue Authority'. The main heading is 'Human Tissue Authority Portal'. Below this, a breadcrumb trail reads 'You are here > Home'. A left-hand navigation menu titled 'Self Service' includes links for 'Licence applications', 'Quality and safety (organs) regulations application', 'Licence #30108', 'Reporting', 'SAR Report', and 'SAE Report'. The main content area is titled 'Details for Licence Number #30108' and features four tabs: 'Licensed Premises' (selected), 'Designated Individual', 'Person Designated', and 'Satellite Sites'. Under the 'Licensed Premises' tab, the following information is displayed: 'LICENSED PREMISES', 'Licensed Premises Name : Human Tissue Authority3', 'Licensed Premises address : Finlaison House, London, SW1W 9SZ, England', and 'Primary Telephone Number : 02072691900'. Below this, the 'LICENSED SECTORS' section lists 'Human Application'. At the bottom of the page, there are links for 'Disclaimer', 'Privacy policy', 'Terms and conditions', and 'Logout', along with the text 'An independent statutory regulator sponsored by DH Department of Health'.

## Report a serious adverse event or reaction

Designated Individuals and Persons Designated can report a serious adverse event or reaction by selecting the relevant licence number and then selecting 'SAR Report' for serious adverse reactions or 'SAE Report' for a serious adverse event.

More information about serious adverse events and reactions can be found on our [website](#).

Once you have selected the SAR or SAE report there are three sections:

- Create a new report
- Resume a saved submission (note that forms are automatically saved between pages)
- View previous submissions. Follow up reports are related to previous submissions. See 'Submitting a follow up report' on page 9 of this document for more details.

The screenshot shows the Human Tissue Authority (HTA) portal interface. At the top left is the HTA logo with the text 'Human Tissue Authority'. The main heading is 'Human Tissue Authority Portal'. Below this, a breadcrumb trail reads 'You are here > Home'. On the left side, there is a 'Self Service' menu with the following items: 'Licence applications', 'Quality and safety (organs) regulations application', 'Licence #30108', and 'Reporting' (which includes 'SAR Report' and 'SAE Report'). The main content area is titled 'SAR Report' and contains three sections: 'Create a new SAR Report' with a button 'Click here to submit a new: SAR Report', 'SAR Report in Progress' with the text 'There are currently no in progress forms to display', and 'Previous SAR Report Submissions' with the text 'There are currently no previous form submissions to display'. At the bottom right, it states 'An independent statutory regulator sponsored by DH Department of Health'. At the bottom left, there are links for 'Disclaimer', 'Privacy policy', 'Terms and conditions', and 'Logout'.

Once you have submitted the serious adverse event or reaction you will be given a case number. The case number will also be sent to your registered email address.



## Human Tissue Authority Portal

You are here » Home » SAR Report

### SAR Report

Thank you.

Your case reference number is: CAS-21823-GXH8

**Self Service**

- » Licence applications
- » Quality and safety (organs) regulations application
- » Licence #30108**
- » Reporting
  - » SAR Report
  - » SAE Report

[Disclaimer](#) [Privacy policy](#) [Terms and conditions](#) [Logout](#)

An independent statutory regulator sponsored by 

## Viewing and downloading previous submissions

Previous submissions can be viewed, printed and downloaded by clicking on either SAE or SAR Report and finding the relevant submission under previous submissions. If you have submitted a follow up report this will also be available to view, print and download.



# Human Tissue Authority Portal

You are here » Home

## SAR Report

- » Create a new SAR Report
  - Click here to submit a new: SAR Report
- » SAR Report in Progress
  - Date form started : Tue, 02/10/2012 - 11:19 ..... [Complete saved form](#)
- » Previous SAR Report Submissions
  - CAS-21823-GXH8
    - Date submitted : Wed, 03/10/2012 - 12:03
    - [View form submission](#) | [View follow up](#)

Disclaimer Privacy policy Terms and conditions Logout

An independent statutory regulator sponsored by 

Home » SAR Report » Submissions

## Submission #701

[Download PDF](#)

**This form provides access to the HTA's system for the reporting of any serious adverse reactions that are linked to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells.**

**Please note that if you are not undertaking activities relating to material for human application, for example you carry out post mortem or anatomical examinations, this system is not applicable to you.**

**If you would like further guidance on whether your establishment can report using the system, please contact a member of the serious adverse events and reactions team, on 020 7269 1900 or [saeers@hta.gov.uk](mailto:saeers@hta.gov.uk)**

Reporting serious adverse events and reactions:

Under the European Union Tissue and Cells Directive (EUTCD), the HTA is required to set up a system for tissue establishments to report serious adverse events and reactions. The definitions of serious adverse events and reactions as set out in the EUTCD are as follows:

Serious Adverse Event (SAE)

'serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

Serious Adverse Reaction (SAR)

'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

### Organisation Details Page

<b>ORGANISATION DETAILS (SAR)</b>
<b>Name of Licensed Establishment</b> Human Tissue Authority3

## Submitting a follow up report

Follow up reports can be submitted by finding the previous submission and using the 'create follow-up report' link. If you have several cases but do not recall the case number you can view the previous submission to ensure you are submitting a follow up report for the correct case.



# Human Tissue Authority Portal

You are here » Home

## SAR Report

**Self Service**

- » Licence applications
- » Quality and safety (organs) regulations application
- » **Licence #30108**
- » Reporting
  - » SAR Report
  - » SAE Report

» **Create a new SAR Report**

---

Click here to submit a new: [SAR Report](#)

» **SAR Report in Progress**

---

Date form started : Tue, 02/10/2012 - 11:19 ..... [Complete saved form](#)

» **Previous SAR Report Submissions**

---

CAS-21823-GXH8

Date submitted : Wed, 03/10/2012 - 12:03  
[View form submission](#) | [Create follow up](#)

An independent statutory regulator sponsored by  Department of Health

[Disclaimer](#) [Privacy policy](#) [Terms and conditions](#) [Logout](#)