Guide to reporting SAEARs using the Human Tissue Authority Portal

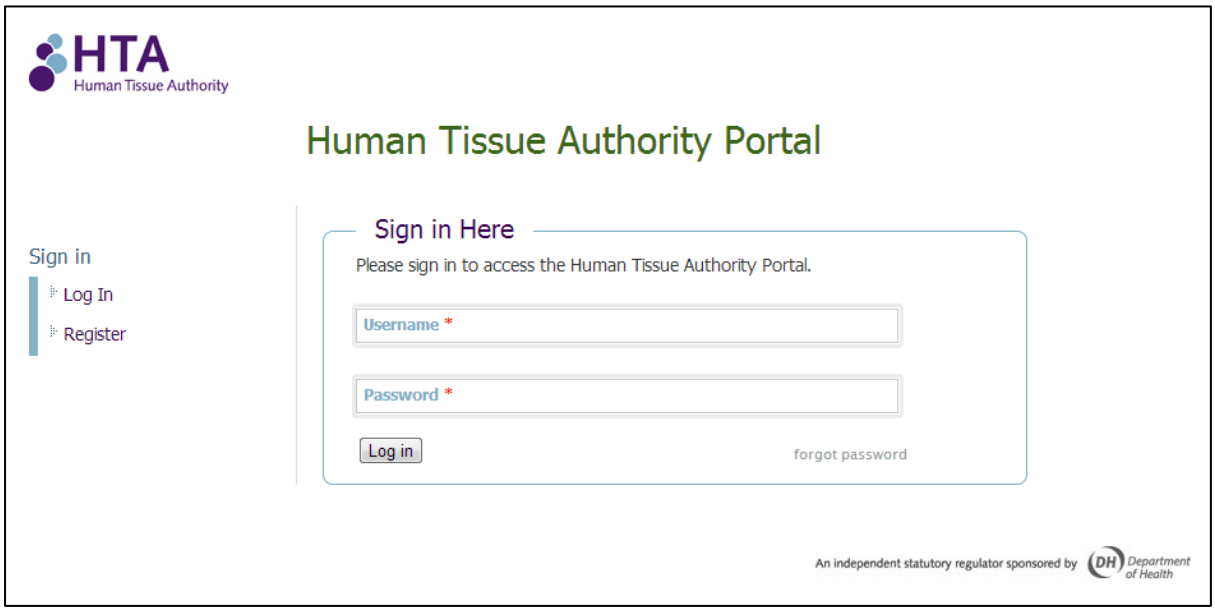
About the Portal

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:



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.

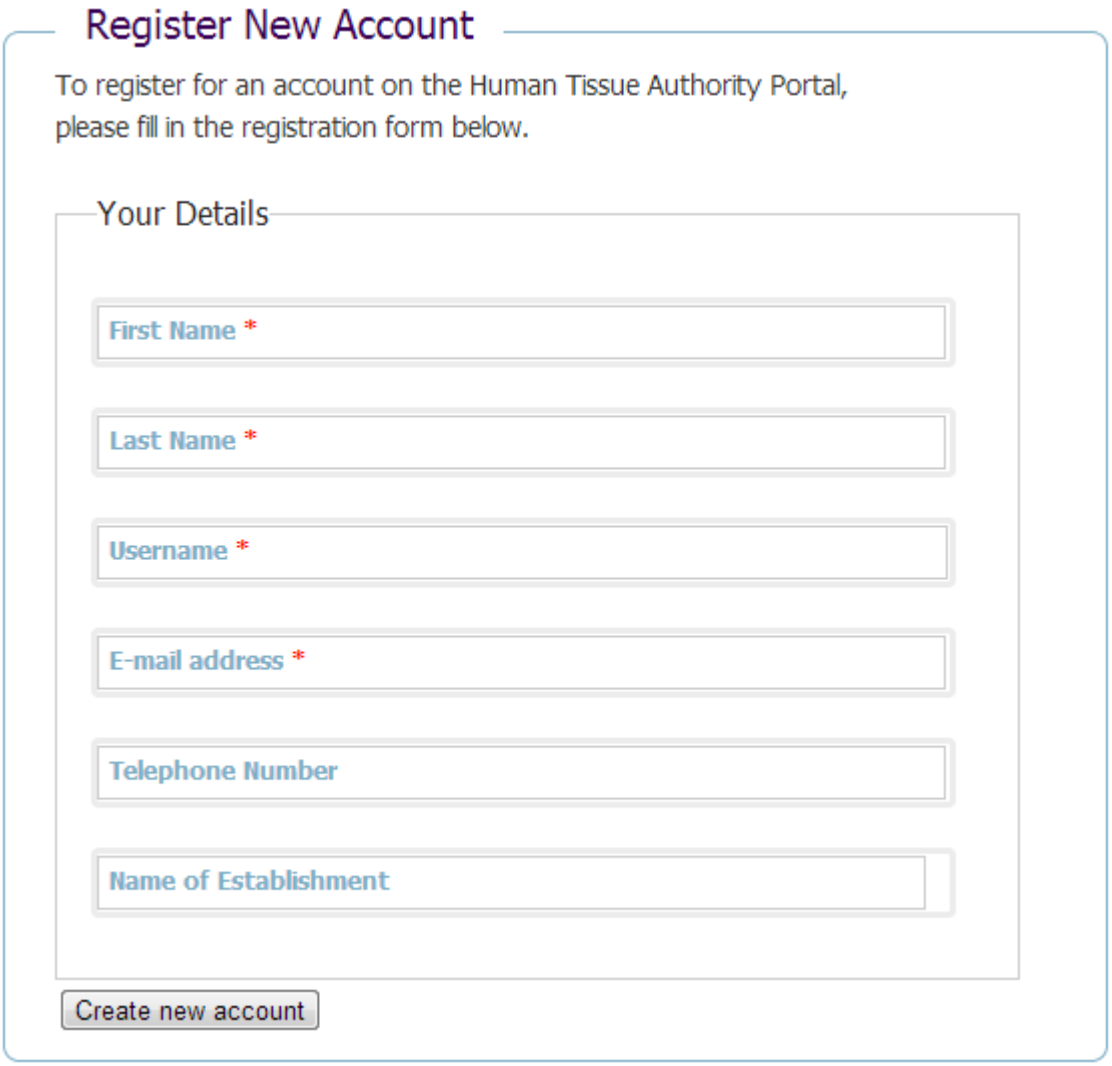
If you have forgotten your password you can reset your password by using the 'Forgot password' link.

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.

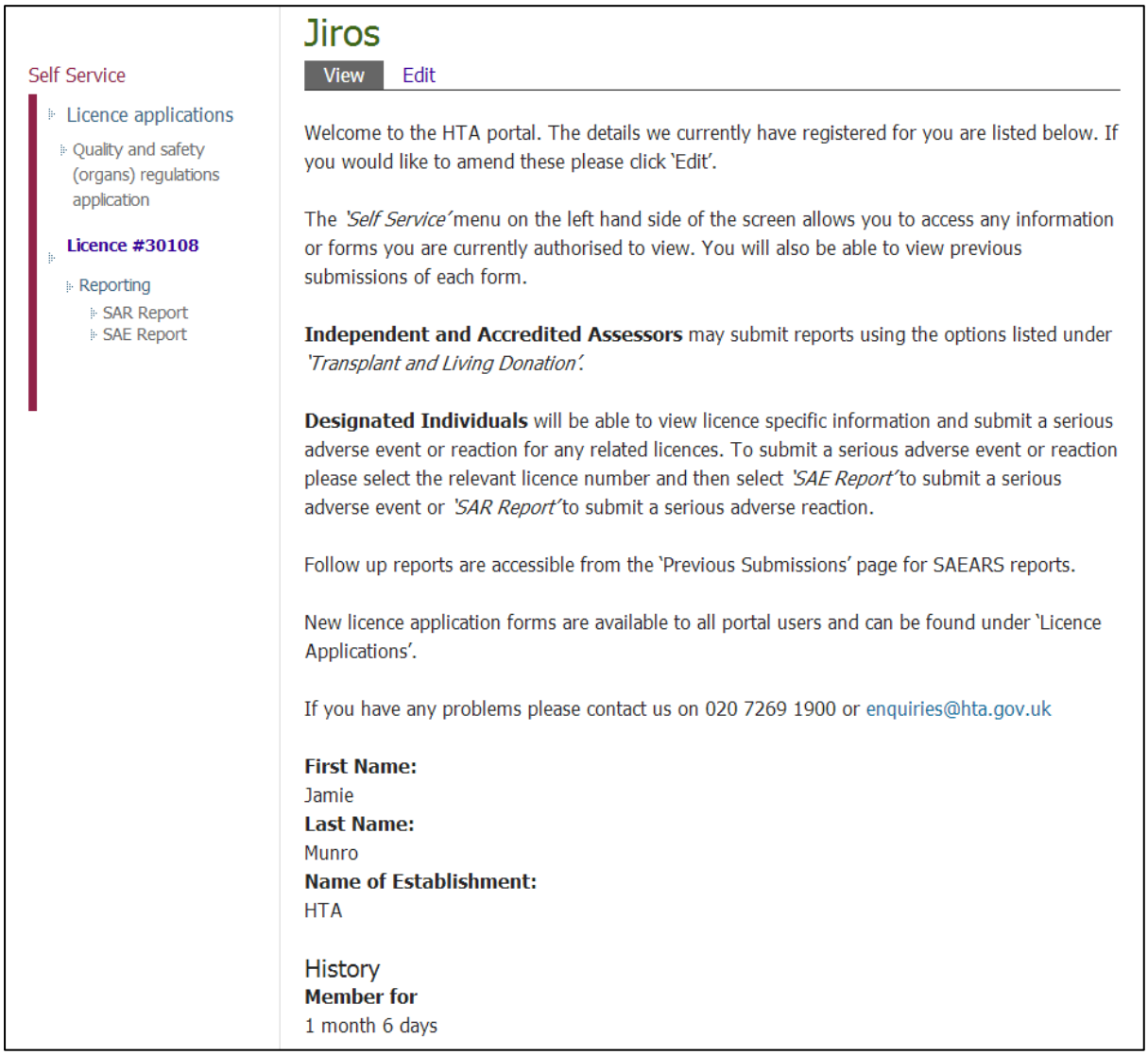
Registration is simple but your account will need to be verified by a member of the licensing admin team. This will only take place during the HTA's office hours, which are Monday to Friday 9am to 5pm. You should register as soon as possible to ensure there are no delays if you need to report a serious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

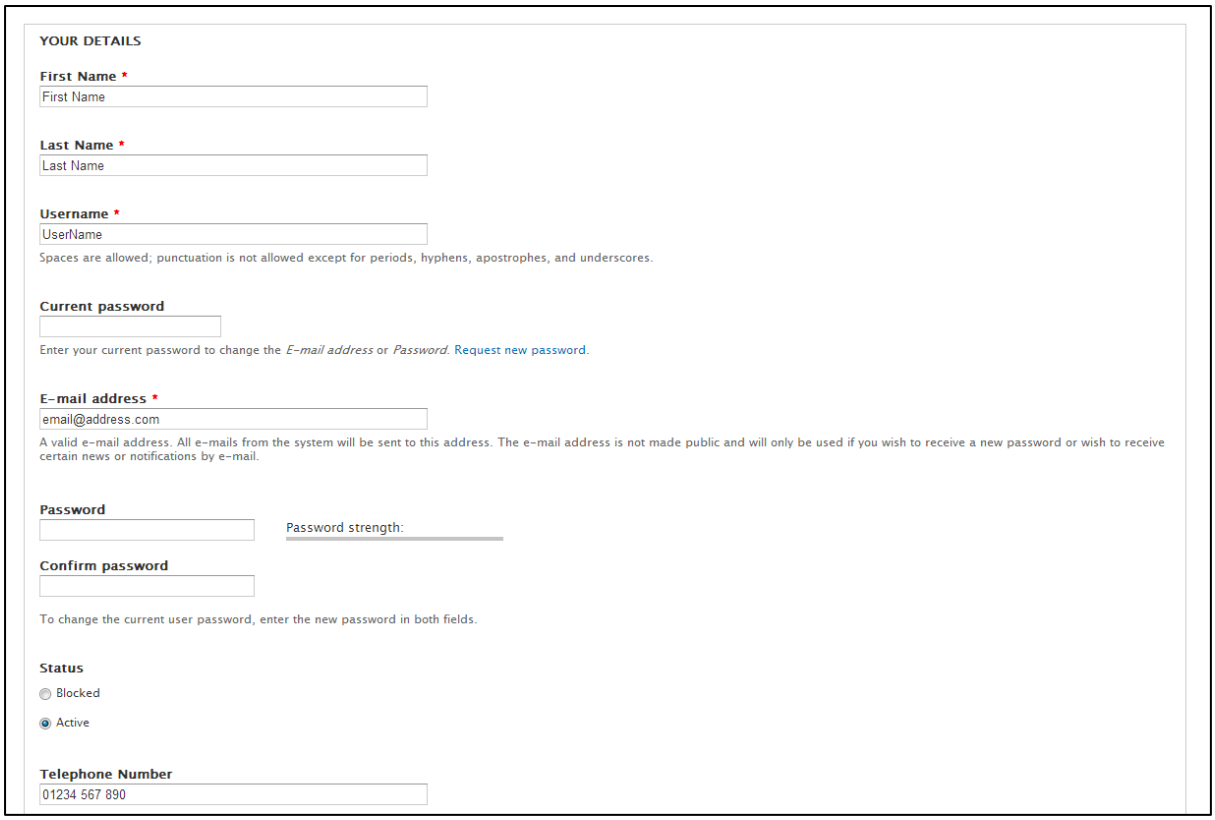


Managing your user account

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'.

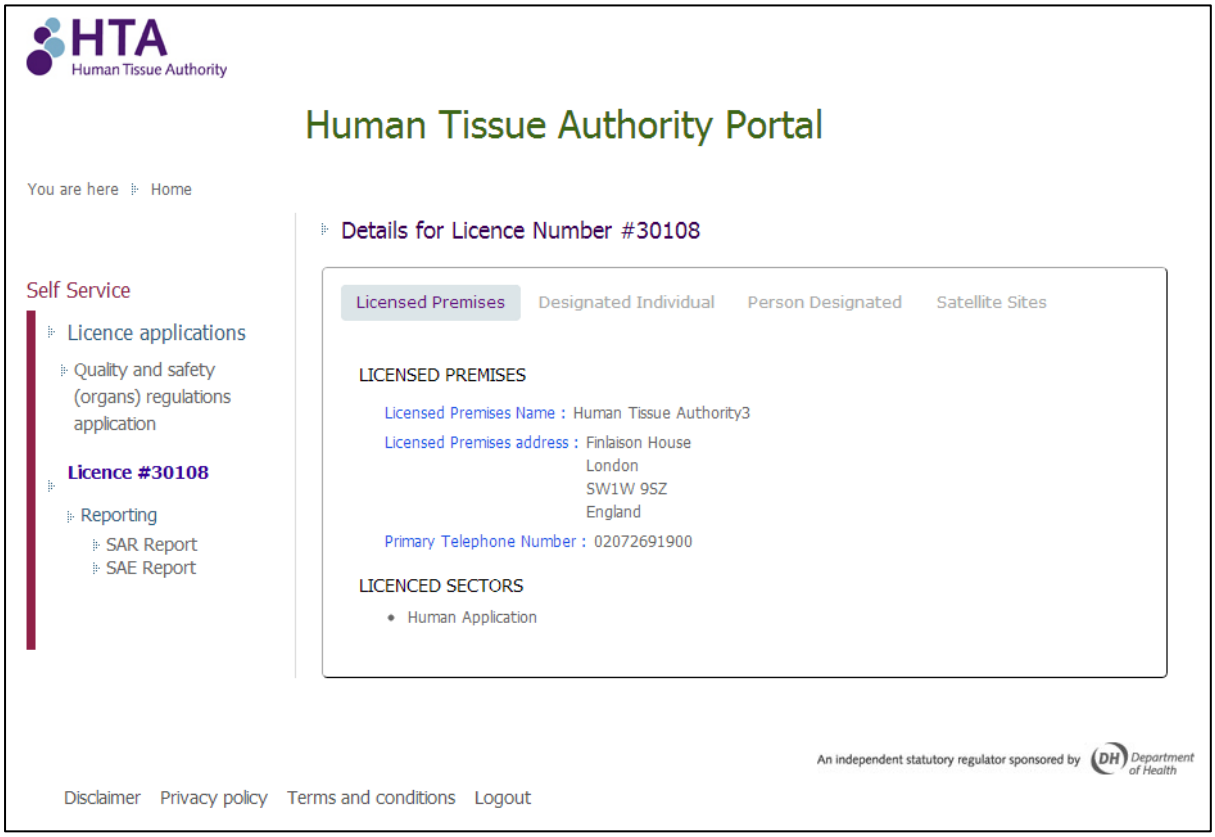


To change your password, or to amend any of your user account details click on ‘Edit’. In order to change your password you will need to provide your current password.



Your 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 though the Portal but for now you will need to follow the existing process for varying information on a licence.



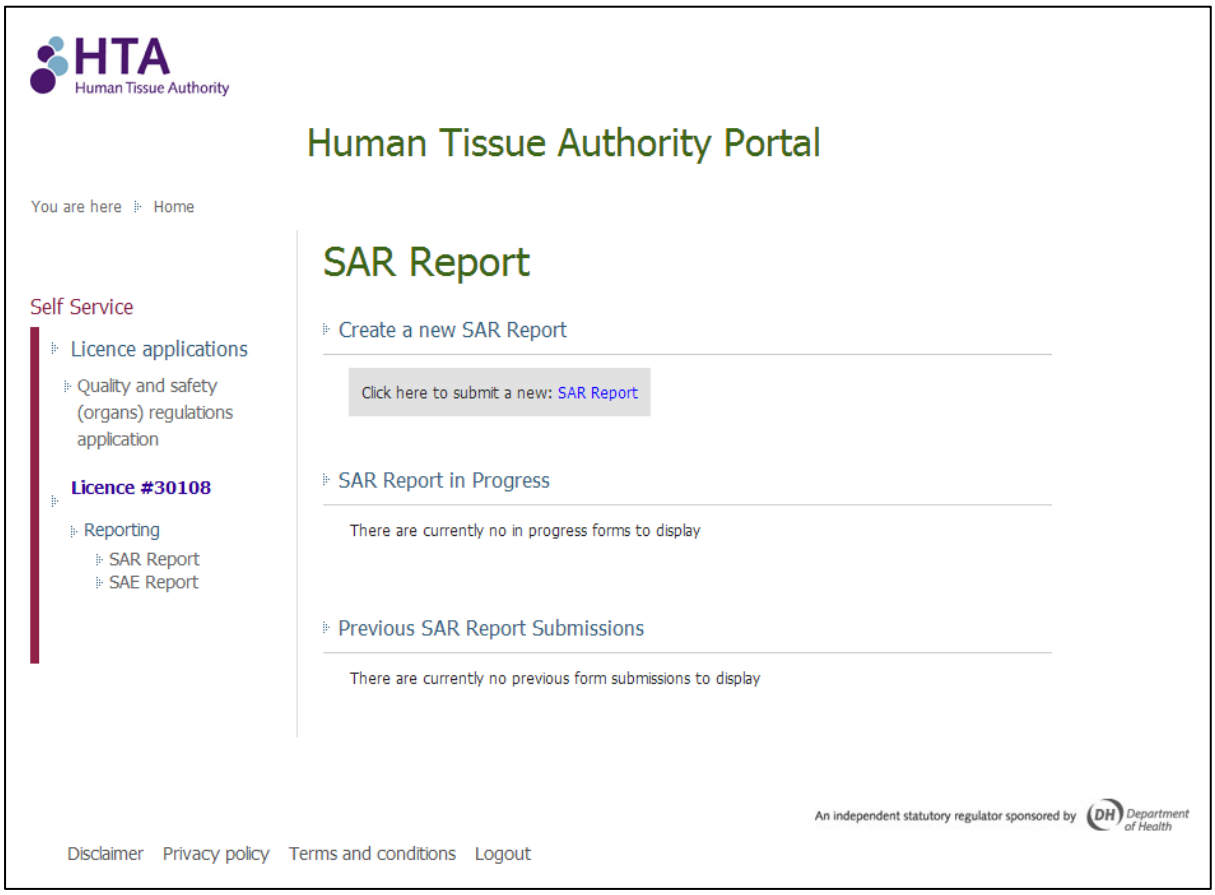
Report a serious adverse event or reaction

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.

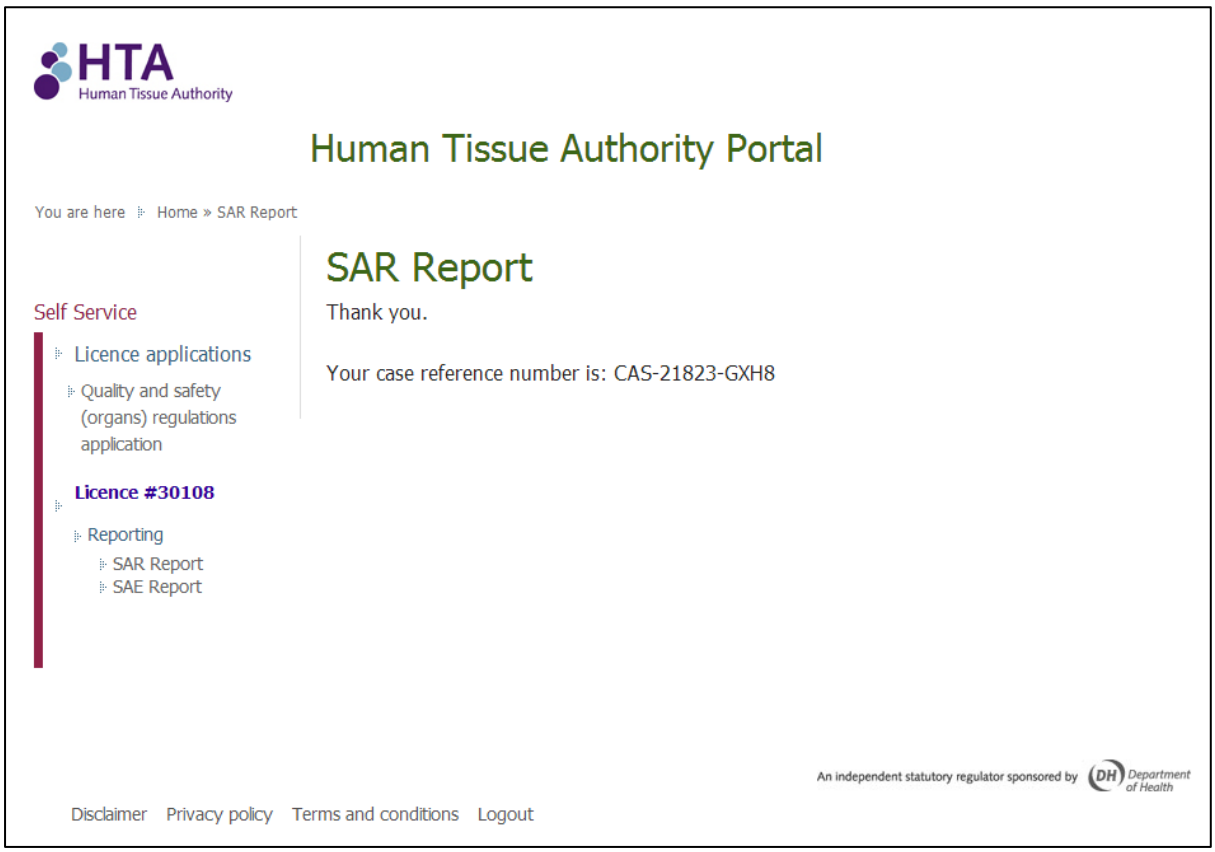
More information about serious adverse events and reactions can be found on our website.

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.

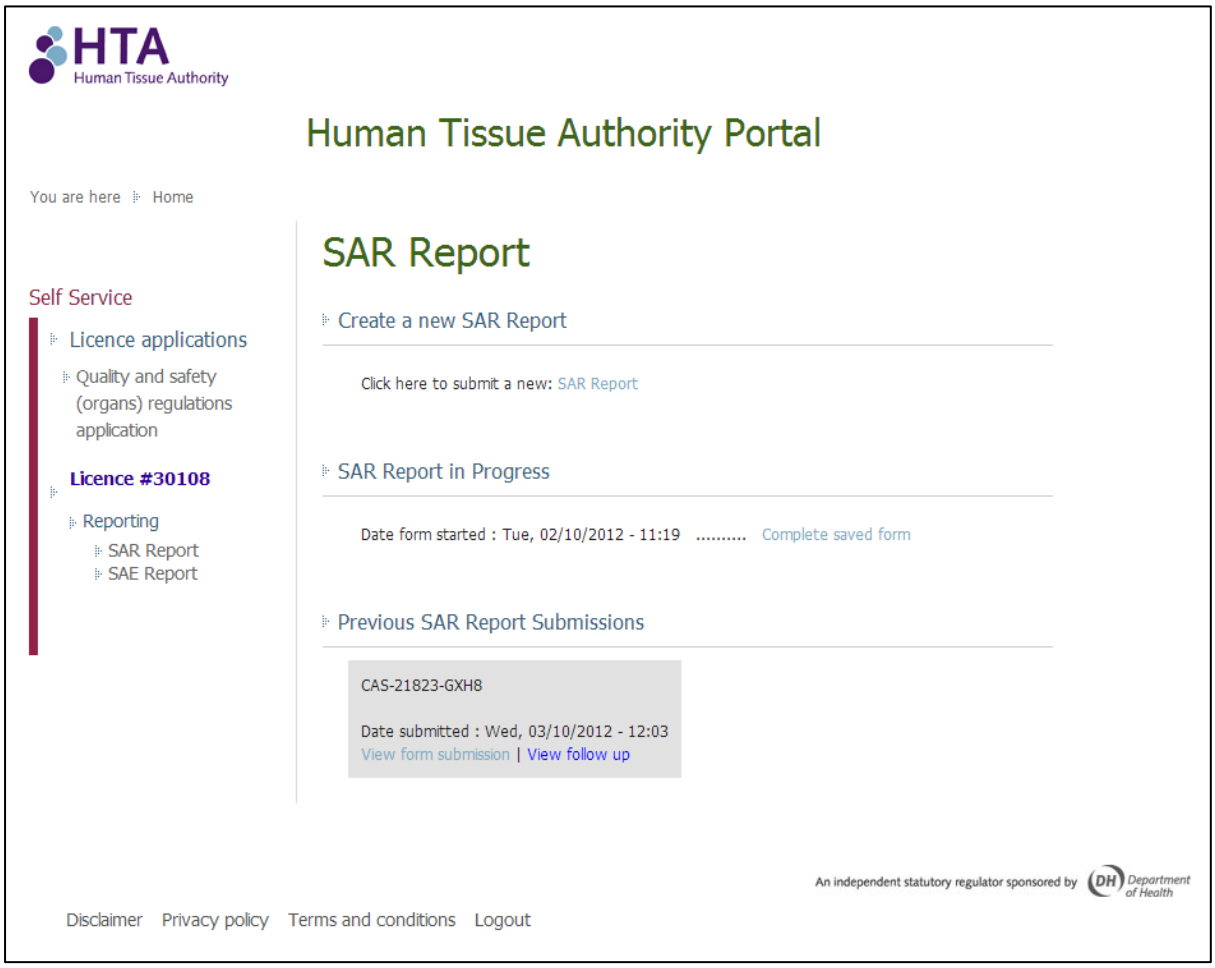


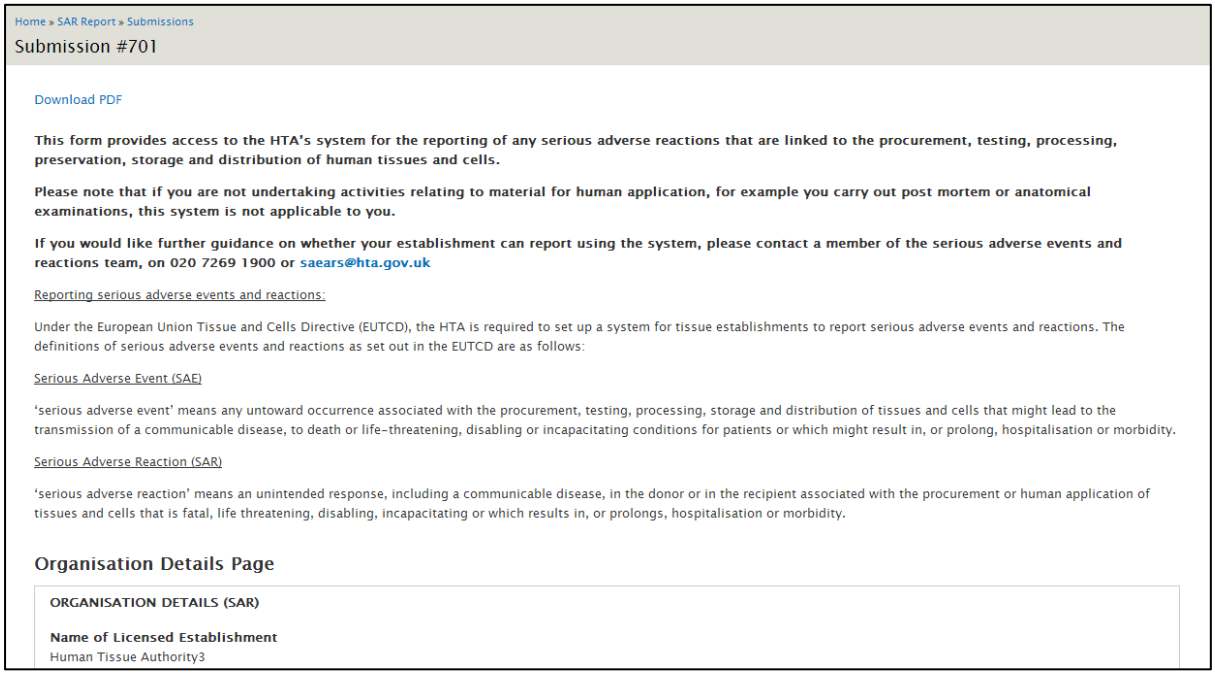
Once you have submitted the serious adverse event or reaction you will be given a case number. The case number will also be sent to your registered email address.



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.





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.