

## Living organ donation (LOD) assessments

## Portal user guide for Independent Assessors (IAs)

## Accessing the portal

The <u>HTA portal</u> is accessible via the homepage of the <u>HTA website</u> (top right hand side of the page). Once you click on the link to access the portal, the login screen will look like this:

<b>FITA</b> Human Tissue Authority The regulator for human tissue and organs
Home / User Account
User Account
Create new account Log in Request new password
Please sign in to access the Human Tissue Authority Portal. Username *
Use mane
Password *
Log in

You need to enter your email address into the 'username' field and your password into the 'password' field. You will then be logged into the portal.

**Please note:** Newly accredited IAs who have completed IA training will need to <u>register for access to the portal</u> or by selecting "Create new account" on the login screen. Once your details have been registered, access to the IA report section will be available within five working days.



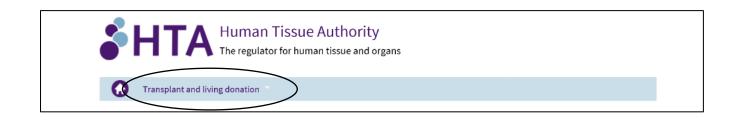
Once you log into the portal, the screen will look like this:

H	TA Human Tissue Authority The regulator for human tissue and organs
Trans	splant and living donation
Welco	me
	just registered a new account please note that it can take up to 24 hours for your account to be verified and for you to be opriate access to your forms. If you have an urgent report to submit please call us on 020 7269 1900.
If you are a	Designated Individual or Person Designate you will find your forms listed under your licence number in the menu above.
If you are a	n Independent Assessor or Accredited Assessor you will find your forms listed under 'Transplant and living donation'.
You are adv well as nun	<i>v</i> ised to change your password frequently and to use a strong password that combines upper case and lower case letters as nbers.
You can cha	ange your password in your <mark>User Account</mark> settings.
	not share your login details with anyone else. If someone in your team needs to submit reports they will need to register for ccount first.
-	any portal related questions or problems you can contact us via our website, by emailing licensing.enquiries@hta.gov.uk or Is on 020 7269 1900.
regulate. Al Assessors s	oduces a newsletter every two months which offers an overview of news, activities and information about the areas we Il Designated Individuals, Organ Donation and Transplantation named contacts, Independent Assessors and Accredited hould receive this automatically but if you do not receive it please contact us via our website. Persons Designate and Licence Holders can <mark>register to receive the newsletter here.</mark>
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## Creating and accessing IA reports

To create a report, click *'Transplant and living donation'* at the top of the screen. An orange banner will appear, please select the option that says *'Independent Assessor Report'*.







This area allows you to:

- create a new report;
- return to reports that are in progress; and
- access reports which have been submitted (these are locked and not editable).

You can return to this area at any time during report drafting by clicking *'Transplant and living donation'* at the top of the page once you have saved your draft.

There is no limit on the number of reports that can be saved as a draft version. If you wish to delete a draft version, please contact the HTA at <u>transplants@hta.gov.uk</u>.

## Creating a new report

Under the heading 'Create a new Independent Assessor Report' please select the 'Click here to submit a new application under: Independent Assessor Report' button to create your report. The screen will look like this:





You are now ready to create your report. A detailed guide about the information IAs need to provide in each section is provided <u>in the table below</u>.

When each page is complete, press the '*Next page* >' button at the bottom of the page. You will not be able to press the '*Next page* >' button if mandatory information highlighted with this symbol (\*) has not been entered, a prompt will appear on the screen to remind you to complete the section you have missed.

## Saving your report

The '*Next page* >' button also acts as a save button, so each time you press it, the information entered up to that point will be saved.

# If you are logging out before you have submitted the report, you must click *'save draft'*. If you do not do this, any work you have completed up to that point will be lost.

When you click the '*save draft*' button, the system will automatically take you back to the top of that page. The message at the top of the page will say '*Submission saved. You may return to this form later and it will restore the current values*'.



## Summary of report sections:

Report section	Mandatory information
	In this section, IAs are asked to confirm the date of the independent assessment, and that they have read, understood and applied the guidance issued by the HTA.
Section A – Category of transplant	IAs are asked to confirm the type of organ being transplanted and if the transplant will be taking place in Scotland. If yes, please indicate this in the report to ensure you see the relevant report sections for Scotland.
	This section asks the IA to confirm the category of the transplant (eg. directed), which determines how the case will be assigned by the LOD team. If you have any concerns about the donation category in the referral letter, please contact the LOD team to clarify any issues.
Section D	Details of the donor, recipient (or partner) and the transplant unit / centre must be entered here. IAs are asked to ensure the names of the donor and recipient are spelt correctly and match the referral letter to avoid any unnecessary delay in the HTA LOD Team assessing the case
Section B – Details of donor, recipient / partner and location of	If there are two Living Donor Coordinators in a unit, please include both their names to make sure the approval is sent to both.
transplant	Only establishments licensed under the <i>Quality and Safety (organs) regulations</i> will be listed here. If an establishment or contact does not appear in the list, please contact the LOD team.



Report section	Mandatory information
	IAs must confirm they have seen suitable identification to ensure they are interviewing the right people, or provide the reasons why this was not possible.
Section C – Evidence of identity and status of relationship	Evidence of the relationship must be confirmed by the IA and indicated in this section. A drop down list of relationships is provided. If these options are not appropriate, IAs can select <i>'Other'</i> and write the relationship in the box below. IAs must explain the evidence they have seen to prove both the identity and the relationship of the donor and recipient. <i>This section is</i> <i>not relevant for non-directed altruistic cases.</i> For directed altruistic donation cases, IAs must provide
	information on how the donor and recipient came to know of each other and provide an explanation on how the offer of donation arose.
	In this section, IAs are asked to confirm whether the registered medical practitioner responsible for the donor confirmed that the donor has capacity or competence to make the decision to donate their organ or part organ.
Section D – About the donor	<ul> <li>The IA must confirm that the donor is:</li> <li>An adult with capacity to understand the donation process in order to consent, or</li> <li>A child.</li> </ul>
	The IA must also state whether they have any concern about the donor's capacity to understand the nature of the medical procedure and the risks involved; and their understanding that they can withdraw their consent.
Section E – Communication	This section should be used to highlight any communications difficulties with those interviewed and how these were overcome.



Report section	Mandatory information
	If a translator has been required, please include their details and confirmation that they are independent.
	The IA must provide information on the donor's understanding and acceptance of the <b>nature of the</b> <b>procedure</b> and the <b>risks</b> involved in donating an organ. If the referral letter states that there are risks <b>specific</b> to the donor, this must be explored in the interview. The IA must provide information that the donor understands any risks specific to them.
	In Scotland only, the IA must provide information that the donor has considered the wider implications of donating, including the effect on any children or dependent relatives.
Section F – Understanding of the nature of the procedure and the risks involved	<ul> <li>The IA must confirm the following: <ul> <li>that mandatory information was included in the referral letter.</li> <li>that the donor understands that that are able to withdraw consent and does not wish to do so at present.</li> <li>that the donor and recipient (or partner) were seen separately and together.</li> <li>what the donor would like to happen to their organ in the unlikely event that it cannot be transplanted into the intended recipient. If the donor has consented to their organ being re-implanted, the IA must confirm the donor's understanding of the additional risks associated with re-implantation of an organ and the expected function of the organ following re-implantation.</li> </ul> </li> </ul>
	The medical practitioner's details must also be provided in this section.



Report section	Mandatory information
	The information provided in this section is crucial as it goes towards the HTA's judgement of whether valid consent is in place, therefore it is essential that IAs include details from the actual conversation in this section to evidence the donors understanding.
Section G – Please refer to the information on Section G according to the relevant donation category	<ul> <li>Directed and directed altruistic cases: Section G – Duress, coercion and reward</li> <li>IAs must detail the discussions had during the interviews with the donor and the recipient in order to determine (as far as possible) that:</li> <li>There was no evidence of duress or coercion affecting the donor's decision to give consent (in Scotland this must also confirm there was no evidence of duress or coercion affecting the decision of the recipient to accept the organ in question);</li> <li>There was no evidence of an offer of a reward that would affect the donor's ability to give consent.</li> <li>The report must contain any evidence of duress or coercion or reward affecting the decision to give consent.</li> <li>Where the IA has not witnessed any evidence of duress, coercion or reward, the IA must still detail that this is the case. There must be sufficient evidence for the HTA to exercise an independent judgement in considering whether we can be satisfied that no reward has been or will be given and that there is no duress, coercion. It must include not only that the IA reached a conclusion that there is/isn't evidence of duress, coercion and reward, but also the rationale as to why the IA has reached that conclusion. Therefore, it is important to include details from the actual conversations had with the</li> </ul>



Report section	Mandatory information
	parties involved. This evidence can be in the form of direct answers provided by the donor and recipient and details of the discussions between the IA and the donor or the recipient.
	The IA must also include their observation of the pair in the joint interview, you may comment on how the offer of donation came about and the body language and interaction between the donor and recipient.
	IAs must also confirm if they have received a signed donor declaration or the reasons why this has not been provided to the IA by the donor.
	IAs are also given an opportunity to draw to the HTA's attention any other issues which may be relevant to the case decision and are not covered elsewhere in the report. The IA should inform the HTA of anything that has not been captured elsewhere e.g. feelings of concern.
	This is the end of the report for directed and directed altruistic cases.
	<i>Non-directed altruistic cases:</i> Section G – Additional information for non-directed altruistic donation
	The IA must confirm that the donor is aware of the implications of being a non-directed altruistic donor and understands the process.
	<i>Paired / pooled cases:</i> Section G – Additional information for paired/pooled donation
	The IA must confirm that the donor is aware of the implications of being a donor in the paired / pooled



Report section	Mandatory information
	scheme and understands the process and include any evidence of this in the report such as details from the conversation had with the donor.
Section H – Please refer to the information on Section H according to the relevant donation category	<ul> <li>conversation had with the donor.</li> <li>Non-directed altruistic cases: Section H – Duress, coercion and reward</li> <li>IAs must detail the discussions had during the interview in order to determine (as far as possible) that: <ul> <li>There was no evidence of duress or coercion affecting the donor's decision to give consent;</li> <li>There was no evidence of an offer of a reward that would affect the donor's ability to give consent.</li> </ul> </li> <li>The report must contain any evidence of duress or coercion or reward affecting the decision to give consent.</li> <li>Where the IA has not witnessed any evidence of duress, coercion or reward, the IA must still detail that this is the case. There must be sufficient evidence for the HTA to exercise an independent judgement in considering whether we can be satisfied that no reward has been or will be given and that there is no duress or coercion. It must include not only that the IA reached a conclusion that there is/isn't evidence of duress, coercion and reward, but also the rationale as to why the IA has reached that conclusion. Therefore, it is important to include details from the actual conversations had with the parties involved.</li> </ul>



Report section	Mandatory information
	IAs must also confirm if they have received a signed donor declaration or the reasons why this has not been provided to the IA by the donor.
	IAs are also given an opportunity to draw to the HTA's attention any other issues which may be relevant to the case decision and are not covered elsewhere in the report. The IA should inform the HTA of anything that has not been captured elsewhere e.g. feelings of concern.
	This is the end of the report for non-directed altruistic cases.
	<i>Paired / pooled cases:</i> Section H – Duress, coercion and reward
	IAs must detail the discussions had during the interview in order to determine (as far as possible) that:
	• There was no evidence of <b>duress or coercion</b> affecting the donor's decision to give consent (in Scotland this must also confirm there was no evidence of duress or coercion affecting the decision of the recipient to accept the organ in question);
	• There was no evidence of an offer of a <b>reward</b> that would affect the donor's ability to give consent.
	The report must contain any evidence of duress or coercion or reward affecting the decision to give consent. Where the IA has not witnessed any evidence of duress, coercion or reward, the IA must still detail that this is the case. There must be sufficient evidence for the HTA to exercise an independent judgement in considering whether we can be satisfied that no reward has been or will be given and that there is no duress or coercion. It



Report section	Mandatory information
	must include not only that the IA reached a conclusion that there is/isn't evidence of duress, coercion and reward, but also the rationale as to why the IA has reached that conclusion. Therefore, it is important to include details from the actual conversations had with the parties involved.
	This evidence can be in the form of direct answers provided by the donor and recipient and details of the discussions between the IA and the donor or the recipient.
	The IA must also include their observation of the pair in the joint interview, you may comment on how the offer of donation came about and the body language and interaction between the donor and recipient.
	IAs must also confirm if they have received a signed donor declaration or the reasons why this has not been provided to the IA by the donor.
	IAs are also given an opportunity to draw to the HTA's attention any other issues which may be relevant to the case decision and are not covered elsewhere in the report. The IA should inform the HTA of anything that has not been captured elsewhere e.g. feelings of concern.
	This is the end of the report for paired /pooled cases.

Please also refer to the relevant HTA guidance:

- Guidance for Transplant Teams and Independent Assessors
- Guidance for transplant teams, Independent Assessors and Accredited
   Assessors in Scotland



When you have completed your report, you will need to upload the **donor referral letter** and the **signed donor declaration form** and attach this to the case.

**Please note:** If you are unable to upload the referral letter please speak to a Living Donor Coordinator. The letter can be sent via email to <u>transplants@hta.go.uk</u>.

The screen will look like this:

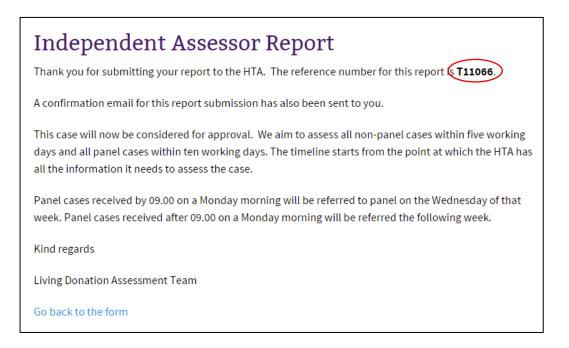
Please upload the following documentary evidence:	
<ul><li>Donor declaration</li><li>Donor referral letter</li></ul>	
Please note: There is a 5mb upload limit on each file.	
If you are unable to upload these documents please send them to the HTA Living Donation Assessment Team in the pre-paid envelope provided	
Please click here to request further envelopes	
Document upload 1 Browse Upload	
Document upload 2 Browse Upload	

The documents can be uploaded in any of the following formats: gif, jpg, png, txt, rtf, html, pdf, doc, docx, ppt, pptx, xls, xlsx, xml, rar and zip.

You now have the option to either submit or save your report. If you wish to submit your report click 'Submit'. The report will be sent to the HTA. If you wish to submit the report later click 'save draft' and you will be able to edit and submit it at a later stage.



Once you have submitted your report, the portal will generate a case number, which will be displayed on the screen. The screen will look like this:



## Once you have submitted your report

#### Notification emails

Once the report has been submitted you will receive an automatic email to confirm that the report has been submitted. The report will then be considered by the HTA Living Donation Assessment Team (LDAT) and assigned to panel where necessary.

The HTA aims to assess all non-panel cases within five working days and all panel cases within ten working days. The timeline starts from the point at which the HTA has all the information it needs to assess the case.

Panel cases received by 9.00am on a Monday morning will be referred to panel on the Wednesday of that week. Panel cases received after 9.00am on a Monday morning will be referred the following week.



Once a decision has been made the IA, Living Donor Coordinator(s) and Medical Practitioner will receive an automatic email containing a link. To view the decision you will need to click on the link and log into the portal. You will then see a list of all the cases you have submitted and the HTA decisions on each of these. The most recent decision will appear at the top of the list.

## Further information required

If further information is required before a decision can be made, a member of the HTA LDAT will call you or send you an email to request this. If this happens, the timeline will then re-start from the point at which you have provided any additional information that the HTA has requested. It is important that you are available to be contacted after you have submitted your report in case the HTA LDAT require any further information.

## Extra functions

- 1. Autosave: The 'Next page >' button at the bottom of the page saves the form every time it is pressed.
- 2. Copy and paste: You can copy and paste from a word document into the form if you would prefer to do so.
- 3. Back button: You can use the '< previous page' button at the bottom of the page to scroll back through the sections of the form. You will not lose any saved information by doing this.
- 4. Spell checker: Please use the spell check option to see any typographical errors made in your report. Use the left click on your mouse to bring up the spell checker.



ABC -

Please provide full details of the donor's understanding and acceptance of the nature of the procedure and the risks involved in donating an organ \*

teh donor siad it will eb a keyhole proecdure which mya convert ot open...|

Please provide full details of the donor's understanding and acceptance of the nature of the procedure and the risks involved in donating an organ \*

teh donor siad it will eb a keyhole proecdure which mya convert ot open...

Please pr	ovide full deta	ils of the donor's understanding and acceptance of the nature of the procedure and the risks involved in donating an
organ *		······································
organ		40
		whole procedure which mya convert of open
	Suggestions	
	said	
	Sid	
	sad	
	shad	
	Siam	
	scad	
Please	Ignore Word	he following information is contained in the donor referral letter to the HTA
	Ignore All	

#### Contacts

For technical issues regarding the portal, please contact our main switchboard number (020 7269 1900) and ask to speak to our IT team. In the event that the portal is unavailable, please use the <u>IA Contingency</u> <u>Report</u> template to submit your report directly to <u>transplants@hta.gov.uk</u>.

If you have any queries regarding the content of the IA report, please do not hesitate to contact the HTA Living Organ Donation (LOD) Team on 020 7269 1900 or <u>transplants@hta.gov.uk</u>.

