

**Donation of whole organs for transplantation**

**Guidance for submitting an Independent Assessor report online**

---

You should read these notes in conjunction with the Guidance for Transplant Teams and Independent Assessors.

Contents list

---

**1 – Introduction**

**2 – Assessment and approval process**

**3 – Decision process**

**4 – Overview of the process**

**5 – Support for the online submission system**

**6 – Contingency**

**7 – Operational instructions**

**8 – Specific guidance for completing the report**

## **1. Introduction**

The Human Tissue Authority (HTA) has created an online system for the submission of Independent Assessor (IA) reports.

The system allows you to write your report electronically and save it as many times as you wish before submitting it to the HTA.

The operating instructions below outline the process for accessing the online submission system and completing your report. Please note that this is a secure system (you should see a padlock in the bottom right hand corner of the screen while the system is open) and given the highly confidential nature of these reports you should not disclose your password to anyone.

Please note that the Scottish legislation is slightly different to that of the Human Tissue Act 2004 which covers England, Ireland and Wales. The detail about living donation in Scotland is set out in the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 and the Adults with Incapacity (Removal of Regenerative Tissue for Transplantation) (Form of Certificate) (Scotland) (No. 2) Regulations 2006. See Scottish Annex on the HTA website<sup>1</sup> for further detail.

## **2. Assessment and Approval Process**

IAs are responsible for interviewing a donor and recipient separately and together producing a report based on that interview, and providing a recommendation to the HTA. The HTA will then make a decision on a case.

Decisions will be made on straightforward live organ transplant cases by the HTA Transplant Approvals Team on the basis of reports and supporting information provided by IAs in individual Trusts (Operating Divisions in Scotland) and transplant units. The HTA Transplant Approvals Team has recourse to member panels, comprising Authority member and experts in transplantation.

Certain categories of transplant must be approved by a panel of HTA members. These are:

- cases involving children (under 18 years old);
- cases involving adults who lack capacity;
- directed paired/pooled donations;
- non-directed altruistic donations;
- novel forms of transplant e.g. adult to adult liver lobe.

The Transplant Approvals Team will act as the liaison between the IAs and the panels.

---

<sup>1</sup> [http://www.hta.gov.uk/db/documents/2006-07-13\\_Scottish\\_Annex\\_to\\_the\\_Codes\\_200607134442.pdf](http://www.hta.gov.uk/db/documents/2006-07-13_Scottish_Annex_to_the_Codes_200607134442.pdf)

### **3. Decision process**

Once you have submitted your report, the HTA will make a decision on the case based on your assessment. You will be notified of this decision by an automatically generated email alert.

The HTA Transplant Approvals Team will provide a decision within 5 working days of a case being referred by an IA.

If the decision is to refer the case to the HTA panel you will be sent a notification of this. The HTA panel will provide a decision within 10 working days of a case being referred by the HTA Transplant Approvals Team.

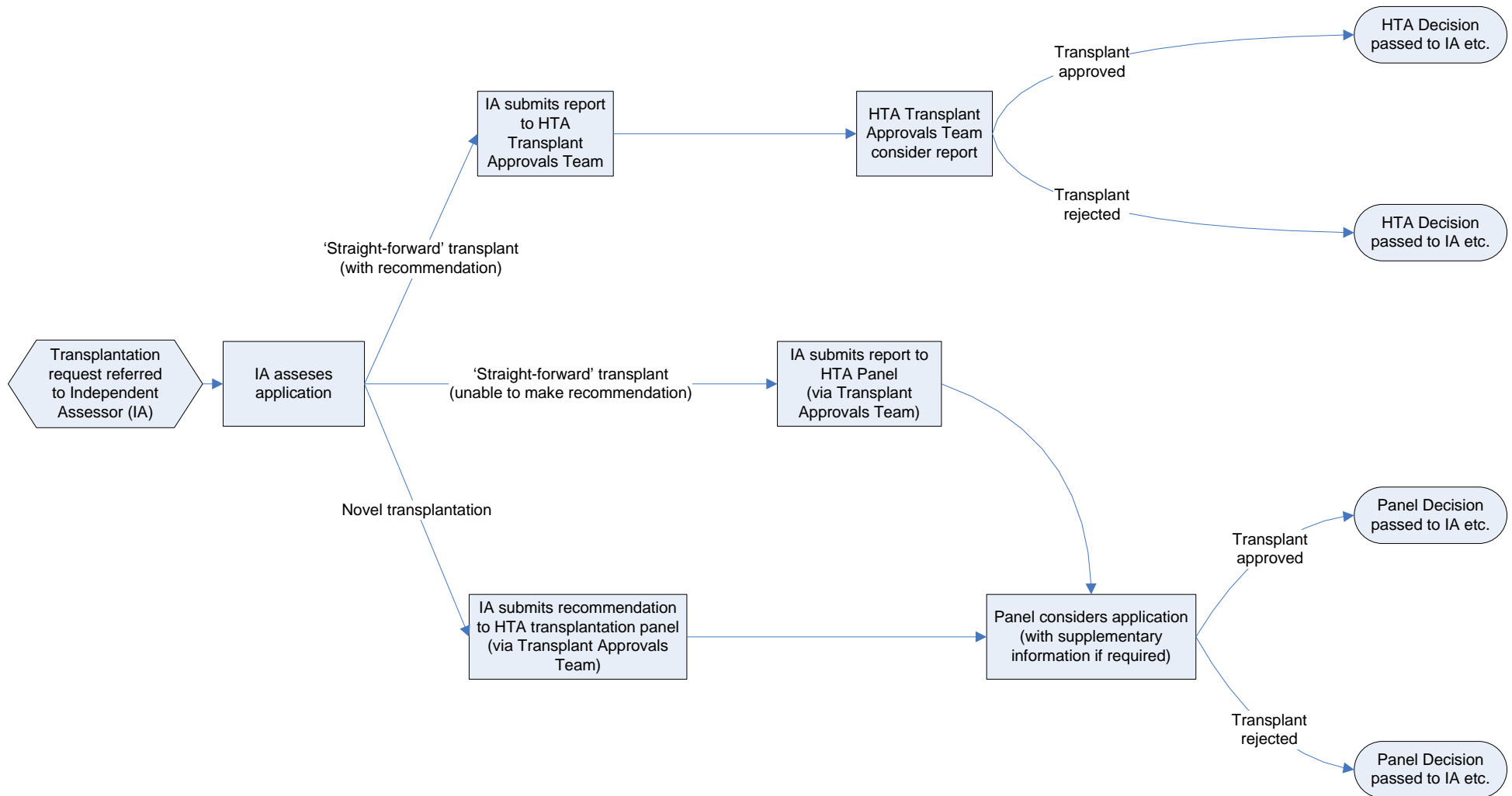
The HTA will also notify the living donor coordinator and the donor's clinician of all decisions at the email addresses you include in the report.

Decisions are valid for **6 months** from the date of the notification email. If surgery does not take place within 6 months then the assessment process will have to be repeated and a new report submitted to the HTA.

### **4. Overview of the process**

The flowchart below shows the various stages of the assessment and approval process and the users involved at each stage.

# HTA Transplantation approval process



## 5. Support for the online submission system

If you experience any problems using the online system please contact the HTA transplant approvals team:

Tel: 020 7211 3400

Email: [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk)

## 6. Contingency system

Should the online system be unavailable for any reason the process for submitting reports will be as follows (the steps should be followed in sequence):

1. If the system cannot be accessed online, assessors should retry after a few hours and if still unavailable, again on the following day.
2. If the system still cannot be accessed, complete a contingency report form which can be downloaded from the HTA website. You can submit this report by email, post or fax.

Email your reports to [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) with **IA Report** in the subject line

Or send a hard copy to:

### **Transplants**

Human Tissue Authority  
15-17 Furnival Street  
London EC4A 1AB

Or send a copy by fax:

Attention: **Transplants**  
Fax number: 020 7211 3430  
Subject: Solid Organ Transplant

If submitting a contingency report form by post or fax, you should notify the transplant approvals team by phone to ensure they receive it.

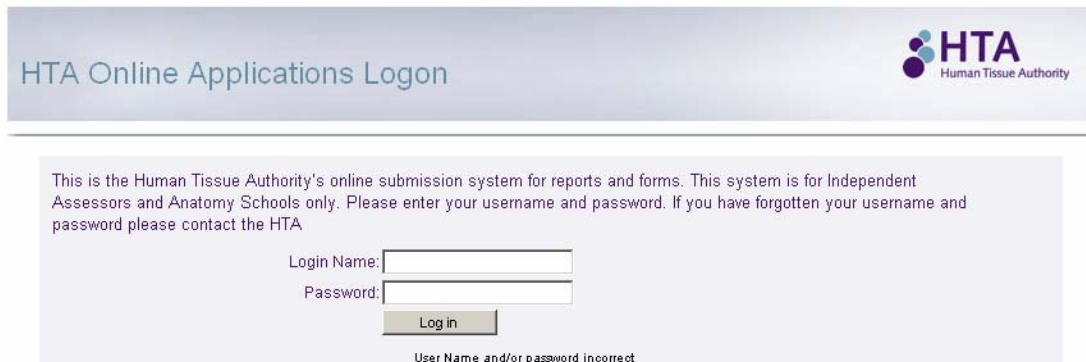
## 7. Operational instructions

Please note that the online system was developed to be compatible with Internet Explorer. However, it is possible to use the system if you have the most recent version (8.1) of Netscape, although the formatting and functionality will appear in a slightly different way than it would if you had Internet Explorer.

If you have an old version of Netscape then it is advised that you upgrade your system to use Internet Explorer. It is also recommended that even if you do have the most recent version of Netscape, it would be beneficial to change to Internet Explorer in order to be able to utilise the system optimally.

### To access the online submission system

- Access the HTA's website at: [www.hta.gov.uk/transplantation.cfm](http://www.hta.gov.uk/transplantation.cfm)
- Click on the link for Independent Assessors and then click on the link on the right hand side which says: [Enter the online submission system for IA reports](#)
- Enter your login and password.



HTA Online Applications Logon

HTA  
Human Tissue Authority

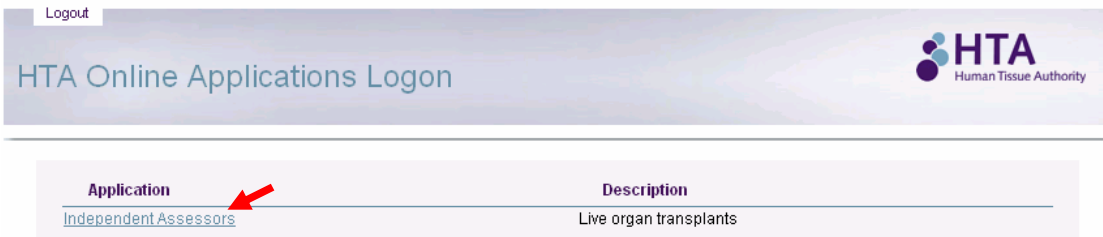
This is the Human Tissue Authority's online submission system for reports and forms. This system is for Independent Assessors and Anatomy Schools only. Please enter your username and password. If you have forgotten your username and password please contact the HTA

Login Name:

Password:

User Name and/or password incorrect

- Select 'Independent Assessors' from the list of applications



Logout

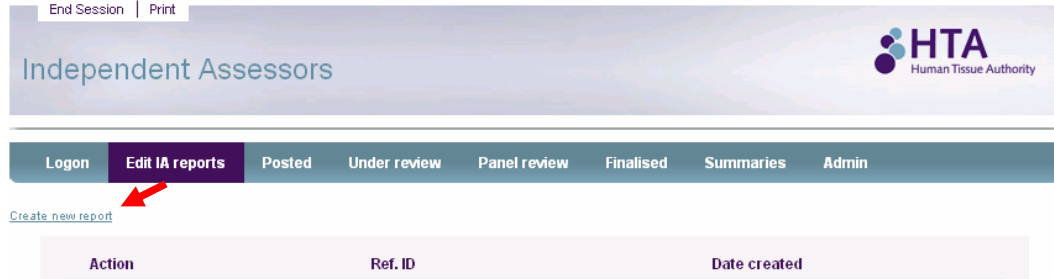
HTA Online Applications Logon

HTA  
Human Tissue Authority

Application	Description
<a href="#">Independent Assessors</a>	Live organ transplants

## To start a new IA report

- Select the 'Edit IA reports' tab.
- Click on 'Create new report'.



End Session | Print

Independent Assessors

HTA Human Tissue Authority

Logon **Edit IA reports** Posted Under review Panel review Finalised Summaries Admin

[Create new report](#)

Action	Ref. ID	Date created
--------	---------	--------------

- A new IA report appears at the top of the list.
- The system automatically generates the reference number for the report. You will receive this via an automatic email alert each time you save or submit a report.
- Click on the new report's reference number to open and edit it.



End Session | Print

Independent Assessors

HTA Human Tissue Authority

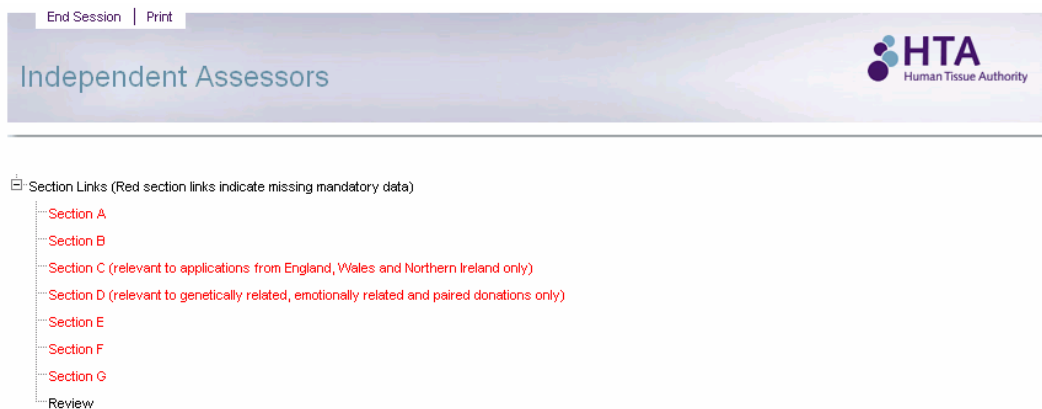
Logon **Edit IA reports** Posted Under review Panel review Finalised Summaries Admin

[Create new report](#)

Action	Ref. ID	Date created
Incomplete	<a href="#">Ref. No: T0340</a>	26/03/2007
Incomplete	<a href="#">Ref. No: T0339</a>	26/03/2007

## Filling in an IA report

- All the sections of the report are listed at the top of the report. If you click on these they will take you directly to that section. Alternatively you can scroll through the report to each section.



End Session | Print

Independent Assessors

HTA Human Tissue Authority

Section Links (Red section links indicate missing mandatory data)

- [Section A](#)
- [Section B](#)
- [Section C \(relevant to applications from England, Wales and Northern Ireland only\)](#)
- [Section D \(relevant to genetically related, emotionally related and paired donations only\)](#)
- [Section E](#)
- [Section F](#)
- [Section G](#)
- [Review](#)

- All fields marked with an asterisk are mandatory. You will not be able to submit the report until all these fields have been completed. You will know if there are mandatory fields in a section which you still need to complete as that section will be in red in the list at the top of the report.
- The fields will only allow you to enter text which is appropriate for that field, for example, you can only enter letters into a field for a person's name or numbers into a field for a phone number.
- Some fields can only be edited if you have chosen the appropriate option before it, for example, you can only fill in the 'other' field after a question if you selected 'other' in the drop down menu immediately preceding it.
- Some fields will automatically populate according to the information held in our system. These include:
  - IA unique identifier
  - IA first and last names
  - IA email address
  - HTA reference number

If any of this information is not correct please amend the field in the report and contact the HTA so we can update our records.

#### Dates

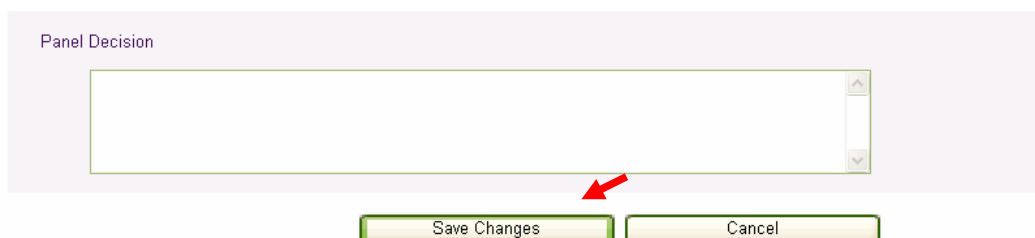
- Fields which require a date to be entered are either free text or require you to select the date from a calendar.
  - For free text fields please fill in the date in the format dd/mm/yyyy
  - For fields with a 'date' button next to them, click the button and select the appropriate date from the calendar then click on 'update'.

#### Dropdown menus


- Please note that after you have selected an item from a drop down menu, you must click outside of the box before using the scroll button on your mouse. If you do not do this you will scroll through the drop down list options and change your selection.

### **To save an IA report**

- To save a partially completed report and return to it later click 'save changes' at the end of the report



- You can get to the save button either by scrolling to the bottom of the report or clicking on the link 'save/cancel' which appears at the top of each section.

**Section F** [Go to save/cancel](#) 

This section refers to the donor and where relevant, (not applicable in Scotland), the other person giving consent.

36. Please give a brief summary of the discussion had with the donor and recipient/ partner to date, in order to determine (as far as possible) that there was no evidence of duress or coercion affecting the decision to give consent, or any evidence of an offer of a reward


37. I confirm that the donor and recipient/partner were seen separately \*

Please check the box to confirm the above statement

Not applicable as donor or recipient / partner is a child under 18 years or an adult without capacity

38. I confirm that the donor understands they are able to withdraw consent at any time and understands consequences of withdrawal for the recipient/ partner. \*

Please check the box to confirm the above statement

**Section G** [Go to save/cancel](#) 

- After clicking 'save' click on 'Return to User Summary'. This takes you back to the main screen.



- An automatic email alert is sent to you confirming that you have saved the report and includes the reference number.
- If you click 'cancel' at the end of the report you will return to the main screen without saving your changes.

**To edit a saved IA report**

- Select the 'Edit IA reports' tab.
- Select the report you wish to edit from the list by clicking on its reference number.
- You can continue to save your amendments as many times as you wish before submitting the report to the HTA.

## To submit an IA report

- Once you have completed all the mandatory fields in a report the entry in the Action column on the left hand side will change from 'Incomplete' to 'Submit data'
- To submit a completed report, select the 'Edit IA reports' tab.
- Click on 'Submit Data' next to the reference number of the report you wish to submit.

End Session | Print

Independent Assessors

HTA Human Tissue Authority

Logon **Edit IA reports** Posted Under review Panel review Finalised Summaries Admin

[Create new report](#)

Action	Ref. ID	Date created
<a href="#">Submit data</a>	<a href="#">Ref. No: T0340</a>	26/03/2007
Incomplete	<a href="#">Ref. No: T0339</a>	26/03/2007

- An automatically generated email alert is sent to you confirming that you have submitted the report and includes the reference number. Please note that once you have submitted a report you can not make any further amendments to it.

## To view a submitted IA report

- Select the 'Posted' tab.
- Click on the reference number of the report you wish to view.

End Session | Print

Independent Assessors

HTA Human Tissue Authority

Logon Edit IA reports **Posted** Under review Panel review Finalised Summaries Admin

Status	Ref. ID	Date created	Date submitted
Submitted	<a href="#">Ref.No.T0340</a>	26/03/2007	26/03/2007
Submitted	<a href="#">Ref.No.T0013</a>	05/09/2006	23/10/2006
Submitted	<a href="#">Ref.No.T0113</a>	11/10/2006	23/10/2006
Submitted	<a href="#">Ref.No.T0116</a>	11/10/2006	23/10/2006

- Please note that you cannot make any further amendments to the report.

## To print an IA report

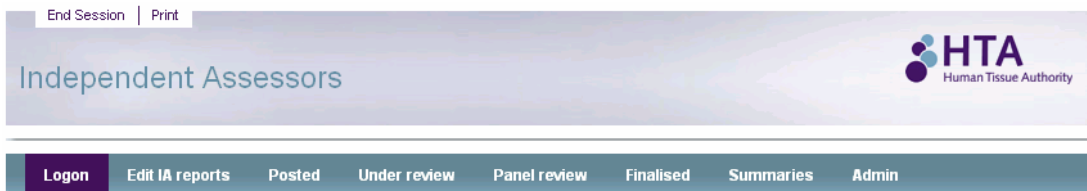
- The 'Print' button at the top of the report allows you to print your report at any stage of the process.



Section Links (Red section links indicate missing mandatory data)

## Searching for reports

- Click on the 'Logon' tab
- There is a search function on this page which allows you to search for a report by either the transplant unit or case reference number.
- Click on the arrow next to the field you wish to search by and select either the unit name or case number from the drop down list.



### Welcome user

First name:	ia
Surname:	user
Organisation:	HTA - Human Tissue Authority

### Search

Transplant unit	<input type="text" value="-select option-"/>	<input type="button" value="v"/>
Ref. ID	<input type="text" value="-Select Ref No-"/>	<input type="button" value="v"/>
User	<input type="text" value="ia user"/>	<input type="button" value="v"/>
<input type="button" value="Search"/>		<input type="button" value="Clear"/>


- The search will filter the list at the bottom of the page to show only those reports which match the criteria you selected.
- To list all of your reports, leave the transplant unit and reference ID fields blank. Check that your name appears in the user field and click on 'Search'
- To view a report, click on the reference number.

## Report submission summary

- Click on the 'Summaries' tab
- Select 'total reports submitted'

End Session | Print

Independent Assessors



Logon Edit IA reports Posted Under review Panel review Finalised **Summaries** Admin

Summary name	Description
<a href="#">Total reports submitted</a>	All reports submitted so far

- A new window will be open which summarises the number of reports you have submitted according to the following criteria:
  - Transplant type
  - Transplant category
  - Your recommendation
  - HTA decision
  - Panel decision

## **8. Specific guidance for completing the report**

Below is specific guidance for some of the questions on the report.

### **General Notes**

In the free text fields, you should aim to provide concise but informative responses. It is important to remember when completing these fields that the information you provide is the only information that the HTA has on which to base its decision on a case. The maximum word limit on these fields is 1500 characters.

### **Section A**

#### **3. and 8. NHS/CHI number**

The CHI (Community Health Index) number is often used in Scotland as the unique patient identifier

#### **4. Type of transplant**

The HTA has provided a list of dropdown options for the types of transplants which IAs might be expected to assess.

This list is not exhaustive. The 'Other' box is to allow for other possibilities.

#### **5. Category of transplant**

If you select one of the directed donation options (e.g. genetically/emotionally related or paired/pooled) for this question then you must complete questions 6 to 10. In the case of pooled/paired donation you will be completing the details for the donor's partner, not the actual recipient of the organ.

If you select a non-directed donation (e.g. altruistic) please go to question 11.

#### **10. Accompanying narrative**

The written referral from the clinician should contain copies of evidence of the relationship. Details of appropriate documentation to prove a relationship is contained in the Guidance for Transplant Teams and Independent Assessors. All documentation viewed should be noted here.

You may also be requested to provide this information to the HTA as supporting evidence if your case is referred to a Panel.

## **Section B**

### **12. Contact details of the living donor coordinator**

The clinician's referral should include email contact details of the living donor co-ordinator. This is to ensure that s/he can be informed of the HTA's decision.

Please ensure that the correct email address is entered (with the @ sign) as this will be the address we send a notification of the decision to.

### **14. Contact details of the donor's clinician**

The clinician's referral should include email contact details of the clinician responsible for the donor. This is to ensure that s/he can be informed of the HTA's decision.

Please ensure that the correct email address is entered (with the @ sign) as this will be the address we send a notification of the decision to.

### **15. The transplant unit**

The transplant unit is the hospital where the donor is worked up. This will usually be the unit that nominated you.

### **16. The transplant centre**

The transplant centre is the hospital at which the surgery will take place. In some cases this will be the same as the transplant unit.

## **Section C**

Where the prospective donor is a child or an adult without the capacity for consent, the referring unit should seek the advice of a court of law (not applicable in Scotland), prior to referral to the HTA.

### **19. Is the donor a child or adult lacking capacity**

If you select yes then questions 20 to 23 are mandatory. If you select no then please go to Section D.

## **Section D**

The written referral from the clinician should contain a copy of the form HTA IT (DC) if an independent translator has been required (see Section 7 of Guidance document for further detail).

You may also be requested to provide this form as supporting evidence if your case is referred to the Panel.

## **24. Communication difficulties**

If there were communication difficulties with either the donor or the recipient / partner then questions 25 to 28 are mandatory. If there were no communication difficulties go to Section E.

## **28. Type of communication difficulties.**

More than one of the following options may be selected: 'Language', 'Hearing', 'Speech', 'Other'.

If language is selected then questions 29 and 30 are mandatory.

For all other options go to question 30.

## **Section E**

Questions 31 to 33 are mandatory.

Question 33 allows for free text. Please ensure that you provide enough detail for the HTA to be able to make decision on a case.

Question 34 is mandatory for paired/pooled donations and should be completed if you selected paired/pooled in Section A point 5.

Questions 35 (i) and (ii) are mandatory for altruistic donations and should be completed if you selected altruistic in Section A point 5.

## **Section F**

Questions 36, 37 and 38 are mandatory.

Question 36 allows for free text. Please ensure that you provide enough detail for the HTA to be able to make decision on a case.

## **Section G**

All parts of this section are mandatory.

In (ii), one of the 3 options must be selected.

You should also give a summary of why you have selected this choice.