HTA
Human Tissue Authority

Human Tissue Authority
Finlaison House
15–17 Furnival Street
London EC4A 1AB

Tel 020 7211 3400
Email enquiries@hta.gov.uk
Web www.hta.gov.uk

Independent Assessors

Date 14 November 2006

Dear Independent Assessors,

Human Tissue Act 2004 – Independent Assessor process to date

As you are aware, the provisions of the Human Tissue Act 2004 (HT Act) regarding living-donor transplantation came into force as of 1 September 2006 and the online submission system has been operational since that time.

As many of you have now accessed the system, whether to submit forms, take part in the pilot, explore the system, or provide general feedback, we thought it would be useful to provide some clarity on some of the issues that have arisen, as well as a general update on the approval process to date.

Approvals to date

Since the approval process began on 1 September 2006, 73 reports from Indepenedt Assessors (IAs) have been submitted to the Human Tissue Authority (HTA) as at 13 November 2006, all of which have been approved. The average turn-around time for IA reports has been two working days. All of the IA reports to date have been for emotionally/genetically directed kidney donations and as yet, no panel cases have been put to the Authority.

Submitted online reports

It is important to remember that the only evidence on which the HTA has to base their decision is the report provided by the IA. On approximately one in every two occasions the HTA has had to seek further clarification from IAs before being able to adequately assess submitted reports and make the final decision.

The HTA will seek such information via the IA's preferred email address in the first instance. The onus is then on the IA to provide the required information. Whilst the HTA endeavours to provide a decision for straight-forward living donation cases within five

working days, if adequate information has not been received from the IA within this timeframe, then the HTA will be unable to assess the report.

As you know, IAs and the HTA need to work in partnership to try to ensure that the timeframe is realised and donations are not unduly delayed. By providing detailed and accurate information at the outset, a case will receive a decision more swiftly, as the HTA will not be required to contact the IA for further information / clarification.

Part of this is the learning curve involved with a new process, but it is helpful if sufficient time is set aside to ensure that the online report is completed correctly and with enough detail for the HTA to be able to make a decision. In order to achieve this, we encourage you to refer to the guidance notes on the online system as well as the Guidance for IAs when assessing cases and completing your IA reports.

To help you in this endeavour, we have detailed below the main areas that have required further information and/or clarification to date.

- Whether the donor and recipient have been seen both separately and together

When approving applications, the HTA require evidence that the donor and recipient have been seen both separately and together (as per the guidance). This information can be included in the final summary at section G (iii). [Note: this information is not required in cases of child or altruistic donation].

- More information for sections E33, F36 and G (iii)

These sections specifically ask for a **brief summary** and / or **details** to be provided. This is in order for the HTA to be assured that all of the requirements of the HT Act have been fulfilled. As this is the only evidence that the HTA has on which to base our decision, we ask that you provide some detail on how you reached your conclusions. Specific points that have not always been adequately addressed to date in these sections include:

- whether the donor understands and accepts the **risks to the recipient** as well as the risks to the donor;
- whether the donor understands and has addressed the **wider implications** relating to the donation (for example, have arrangements been made for dependent children to be cared for); and
- how the IA has determined that there is no evidence of **duress or coercion**, or any evidence of an offer of a **reward** (this requires more detail than a one line statement that the IA is satisfied that there is no evidence to this effect if we are to comply with the HT Act).

Good example answers for each of these sections is provided at Annex A. These examples have been received by the HTA and may be beneficial in helping you to answer these areas of the report.

New functionality

The online submission system was recently updated to include some additional functionalities aimed at making the system even more user-friendly. Now when you log into the system, a user summary page will appear. This page lists all the reports that you have created, saved and submitted, as well as information about the status of these reports and the decision made. You can click on the reference number for these cases to open the report (note: submitted reports will appear as read only). There is also a new search function on this page which allows you to search from within your own reports by either transplant unit or HTA case number. The search will filter the list at the bottom of the page to show only those reports which match the criteria selected.

In addition, you are now able to access a report submission summary which summarises the number of reports you have submitted according to the following criteria: transplant type, transplant category, your recommendation, and the HTA and / or panel decision. This can be accessed through the 'Reports' tab at the top of the page.

Scheduling of surgery

It has come to our attention that, in some cases, surgery has been scheduled for the donation prior to approval being received from the HTA. Although these dates are usually provisional, sufficient time (that is, more than five working days) should be allowed for reports to be approved by the HTA before surgery is scheduled to commence.

Other questions raised with the HTA

The following outlines some of the other common questions / areas of clarification that have been raised with the HTA:

Cultural awareness

There have been a number of instances where IAs have assessed donors and recipients originating from countries other than the UK, and / or from differing cultural backgrounds. In such cases, answers have been sought with regard to the provision of evidence confirming the relationship of the donor and the recipient, along with clarification with regard to issues of determining whether coercion or reward is evident.

Donor coordinators will have already done their best to obtain the documentary evidence required to ascertain the identity of the donor and recipient, as well as proof of their relationship. However, as an IA, you need to be satisfied that this documentation is acceptable. As you are aware, the HTA's Guidance for IAs notes that birth certificates, passports, marriage certificates, and documents from other relatives (where necessary to show the relationship) are the best forms of documentary evidence. If these are not available, we suggest that alternative evidence should be submitted, for example, statements from a GP or upstanding member of the community who can vouch for the validity of the relationship. If you are still in doubt, please contact the HTA as we will be happy to work through the situation with you and provide advice as necessary.

With regard to issues of coercion, duress and reward, it is important to recognise that people from different cultures may relate differently. It is your role as an IA to see if you can draw out pertinent information on such issues when talking to the donor and recipient both

separately and together. Such conversations should highlight if there is any evidence of duress, coercion and / or reward.

If after conducting your assessment you are still in doubt, it is well within your remit to offer a final recommendation of “unable to make a decision”, or “refer to HTA panel”. In such cases, the HTA can refer the case to a panel of Authority members for a final decision. Any decision is ultimately the HTAs to make, and it should not be viewed negatively if you are unable to make a decision.

Filing requirements

Some IAs have asked whether they need to file the documentation relating to their assessment. The Guidance for IAs makes it clear that there is no requirement to write or file the report in the donor’s case notes, nor is the IA required to keep a copy of their own notes or the report, unless it is a requirement of their trust or they wish to do so for their own records. IAs are able to search for an electronic copy of their submitted report via the online submission database.

HOT testing

For clarification, in the case of genetically related living donor transplants, if the genetic relationship has been proven by the approved HOT tester and the result received by the clinician responsible for the donor by 31 August 2006, then that transplant can go ahead provided it does so before 28 February 2007. After that time, all living organ donations must be assessed by the HTA.

And finally…

Many thanks to all of you for your support in helping to make the transition to the new process as seamless as possible. We hope the information included in this bulletin is useful and we will continue to address issues and enquiries by regular monthly bulletins. In the next bulletin we will also endeavour to include anonymised ‘tricky’ cases that have been received as a useful learning tool.

As you continue to use the online system, you will inevitably have further comments and suggestions for improvements. Please feel free to send these to the HTA, at transplants@hta.gov.uk. We will be considering further developments of the database and guidance, and your feedback on how to make the process more user-friendly and appropriate to your needs would be welcome.

As always, please feel free to contact the HTA should you have any questions. We are always happy to discuss any issues with you as they arise.

Kind regards,

Rebecca Halpin
Transplant Manager

ANNEX A

Good examples of responses to questions

E33: Please provide detail of donor's understanding and acceptance of nature of procedure and risks involved and any other wider implications, for example, the risks to both donor and recipient / partner and the effect upon children and any other dependent relatives

Example 1:

The donor told me that when she heard that her relative had kidney failure she immediately offered one of her kidneys. She has been shown to be able to donate a kidney and she tells me that she is very pleased to be able to do so. She is aware of the risks of the anaesthetic, the operation and post-operative risks. She is also aware of the risks posed to the recipient by the procedure. She is very keen to proceed with the operation. The whole family live in the same local area. They have always been close and she is keen to be able to do whatever she can to help the recipient. I discussed with her the potential risks that family tensions may develop as a result of the procedure, even if things go well. She tells me that the matter has been discussed openly within the family, everybody is supportive and they are all keen for things to go ahead.

Example 2:

In conversation I was able to ascertain that the donor had a good understanding of the nature of the kidney transplant procedure and of the potential risks of the surgery. He was fully cognisant with the fact that he or the recipient could experience complications or die as a result of the surgery. He also had a realistic grasp about the expectations of surgery for the recipient, and was able to explain that he knew that the kidney might reject at an early stage or possibly survive for many years. He had reckoned with these risks and was fully accepting of them. He is currently single and has one child from a previous relationship and who is cared for by the mother. He has thought through the implications that his child or any future children might require kidney donation. There is no other member of the family who has renal problems and he is of the view that he should act on the basis of current need and not on future possibilities which might never arise.

The recipient also has a good grasp of the technical aspects of the operation and of its potential risks. The family including her partner, her mother and father are very close and will provide full support for her child if complications of surgery were to develop.

F36: 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

Example 3:

I interviewed the donor on her own and then with the recipient. The recipient is fully aware of the risks of the procedure, is extremely grateful to the donor for offering her kidney and

although apprehensive about the operation is keen for the operation to proceed. She interacted well with the donor, they were relaxed together and it was clear there was no evidence of any tension, difficulties or anger that might indicate the possibility of any coercion, threats or financial transaction.

Example 4:

The donor told me that the decision to donate a kidney arose out of his own free choice and that he is not subject to any outside pressure or financial inducement. The donor confided his first instinct (when he knew about one year ago that the recipient's renal function had declined to the point of impending dialysis or transplantation) was that he wished to donate a kidney. He told me he had never changed in his desire to help the recipient. The recipient confirmed the view that she and the donor were very close. She told me that on many occasions she had sought to re-assure the donor that he did not need to go ahead with the donation and that she would be happy to go on the cadaveric transplant list, but that on each occasion the donor had confirmed that he was keen to proceed. I could find no evidence of coercion, threats, extortion or financial transactions.

G (iii): Please give a brief summary providing reasons for the choice you have made

Example 5:

I can confirm that I have interviewed the donor and recipient at stated venue on date. I saw them separately and together. As a result of that interview, I can confirm the following:

- The recipient has end stage renal failure and requires transplantation to improve quality of life and to avoid dialysis.
- It is clear from the documentary and observable evidence that the donor and recipient are genetically / emotionally related.
- The donor has offered to donate a kidney through his own choice which is not subject to any outside pressure. There is no evidence of a financial reward.
- The donor and recipient have a good understanding of the risks of kidney transplantation including the wider implications and are both fully accepting of the risks involved.
- Both donor and recipient have a good support network to provide backup if there are any complications after surgery.
- Both are aware that the donor is entitled to withdraw consent until the time of surgery.
- The donor has been evaluated by a medical practitioner and found to be suitable for live kidney donation.

I believe that the above complies with the requirements of the HT Act and it is my recommendation that this case should be approved by the HTA.

Example 6:

Having interviewed the donor and recipient separately and together I am satisfied that both donor and recipient have full capacity to give fully informed consent, they are both fully aware and accepting of the potential risks and complications and they have full support of

the extended family. There is no evidence of any coercion, threats or financial inducement. They are both fully aware that they can withdraw consent at any time up to the point of anaesthetic. I am satisfied that the donor and recipient are genetically / emotionally related. There is therefore no reason for not recommending that the donation be approved.