



# **Guidance for living organ donors on the Human Tissue Authority's independent assessment process**

September 2012

## **Who this guidance is for**

This guidance is for people donating organs (living organ donors). It explains what kind of organisation we are, our role in living organ donation from live donors, and what you need to know before you donate an organ. This guidance also explains the Independent Assessment process. This process includes a form for donors to sign to confirm that they are not receiving any reward (payment or other benefit) in connection with donating an organ.

We recommend that you read this guidance along with the other information provided by the transplant units.

Throughout the guidance we refer to 'organ', which means a kidney or a liver lobe. Although donation of a lung lobe is rare, it may be possible and 'organ' may refer to this also.

## **The Human Tissue Act (2004) and the Human Tissue Authority**

The Human Tissue Act 2004 provides the legal framework for organ donation in England, Wales and Northern Ireland. In Scotland the framework is provided by the Human Tissue (Scotland) Act 2006.

We, the Human Tissue Authority, provide advice and guidance about various aspects of the Human Tissue Act 2004 and make the decision on whether living organ donations in the UK can go ahead.

In the UK, a living donor can only donate an organ if they volunteer to do so and will not receive any payment or reward for their organ. It is our legal duty to make sure that no reward is given, received, offered or sought for the supply of an organ.

Our independent check is in place to reassure everyone that:

- no reward has been or will be given for the donation; and
- the donor has given consent to the removal of their organ.

If these two criteria are met, the transplant can go ahead legally.

## **The HTA independent assessment process**

We have a legal responsibility to make sure that a donor:

- has capacity and / or is competent to give consent
- understands the risks involved;

- is volunteering of their own will and is not being pressurised into donating the organ; and
- will not receive any reward for donating the organ.

We make sure of this through an independent assessment process. We have a team of Independent Assessors throughout the UK who interview donors and the people who will receive their organ (recipients).

If the donor is an adult and does not have capacity to consent, or a child who is not competent to consent; a suitable person can consent to the donation on their behalf. Once the donor's medical assessments are close to completion, the Living Donor Coordinator will arrange an appointment with a HTA Independent Assessor.

The Independent Assessor will need to interview the donor (or the person giving consent on the donor's behalf) and the recipient, both separately and together, to ask them a range of questions about the proposed donation. The donor and recipient will need to bring photo ID to the interview, where possible, so the Independent Assessor knows that they are interviewing the correct people.

If the donor or recipient has any communication difficulties, the transplant team will let the Independent Assessor know so they can make sure appropriate independent support (for example, a translator) is available for the interview.

For non-directed altruistic donation, where the recipient has not been identified, only the donor will be interviewed.

After the interviews, the Independent Assessor will produce a report and send it to us for a decision on whether the donation can go ahead.

By law, there are a number of issues that must be covered during the interview with the donor.

## **What areas will be covered during my interview?**

### ***'Capacity to consent'***

We must be satisfied that the donor has capacity to give consent to the removal of an organ for transplantation. We judge this in a number of ways, but we start by assuming that every adult has capacity unless there is evidence to suggest they do not. In the referral letter to the Independent Assessor, the clinical team will state that you have capacity to give consent.

The Independent Assessor will ask you about your understanding of the operation and the risks involved. It is important that you can show you have some

understanding of the following.

- ***Nature of the medical procedure***

For example, what type of operation you are having, that you will have a general anaesthetic, and that you may have scarring after the operation.

- ***Risks of the surgery***

For example, the potential effect on your health – this may be temporary or permanent. It is important that you know that there is a small risk of death.

- ***The name of the person who gave you information and their qualification to give it***

This information is generally given to the Independent Assessor in the referral letter. The transplant team will be able to confirm the name of the person, if you have forgotten it.

***‘Duress and coercion’***

We must find out whether you are being pressurised into donating an organ. You must be donating an organ willingly and voluntarily.

The Independent Assessor will talk to you about any pressures you are under so they can find out if you are donating of your own free will, or whether you are under such pressure that we cannot consider your consent to be freely given.

The Independent Assessor will also make sure you understand you can withdraw your consent if you change your mind, up until the point of surgery. The Independent Assessor will ask you whether you would like to withdraw your consent but feel unable to. They may talk to you about this at length, and you can speak freely to the Independent Assessor. If you would like to withdraw your consent, you will be supported in doing so.

***‘Reward’***

You must not receive any payment or other reward for donating an organ. This means a reward cannot be:

- given,
- received,
- offered, or
- sought

These four principles are relevant to any person, not just you. This means that you, the recipient, family members, friends and others (such as a service that offers to

supply a donor, or an organ, to a recipient) may commit an offence if they give, receive, offer or request a reward.

We must be satisfied that there is no evidence of reward in all cases of living organ donation.

Any involvement in buying or selling human organs is a criminal offence and could result in a criminal prosecution for which the possible penalties are a fine, a prison sentence, or both.

### **What is meant by ‘reward’?**

In the Human Tissue Act 2004, reward means ‘any description of financial or other material advantage’. In practice, reward means any money, gift or other benefit with a financial value which influences the decision to donate an organ.

Anything that contributes to your decision to donate your organ or tries to persuade you to donate your organ could constitute a reward.

An example of this could be as follows:

Jim’s friend Mark has asked him to donate a kidney. Jim does not like the thought of having an operation and is reluctant to proceed. Mark has suggested that he will offer Jim a job once he has recovered, but only if Jim donates his kidney. Jim has been out of work for some time and decides to proceed, even though he is very anxious about the operation.

You can receive payments to cover your expenses or loss of earnings resulting from you donating an organ. These payments are not considered to be reward.

### **What will I be expected to do?**

Part of the process of determining whether reward is a factor in a donation is for donors to sign a declaration confirming that you have not and will not receive any reward for donating the organ.

This declaration will assure us that you have read the main sections of this guidance, that you understand the law, and to confirm that no reward is associated with the organ donation and transplantation.

## **When will I sign the declaration and how will this be used?**

The Independent Assessor will discuss the declaration during the interview. You should sign it either before or during the interview and hand it to the Independent Assessor.

Once the interview over, the Independent Assessor will send us their report, your signed declaration and the referral letter from the clinical team.

## **Why am I being asked to sign a declaration?**

There is now more awareness of living organ donation than there has ever been, with many news stories featuring people needing an organ, or cases where organ transplants have been successful. There is also an increase in the use of social networking websites which can put potential donors in contact with people who need an organ transplant.

With an increasing demand for organs for transplant, a limited supply, and more ways of donors and recipients coming together, there is a higher risk of people trying to profit from the supply of an organ.

In most cases, a person chooses to donate their organ to improve the health of the person receiving it. Most donors do not intend to receive a reward for their organ.

Unfortunately, we cannot ignore the rare, but very serious, cases where a person chooses to donate their organ for financial or material advantage, or where a person may be forced into donating an organ.

## **How will my personal information be protected and used?**

We will use your signed declaration to help us make a decision about the donation. We will keep the information we get, in line with our policy on storing records. We will make sure your personal information is protected, in line with our data protection policy.

## **Potential difficulties to consider with the signed declaration**

We realise that there are some situations where a donor may not be able to sign the declaration. We have asked clinical teams to tell us if this happens so that we can tell them what to do next.

In cases where a donor lacks capacity to consent, and a suitable person gave consent on the donor's behalf, that person will be asked to sign the declaration.

In cases where a donor was a child who was not competent to give their consent, and a suitable person gave consent on the donor's behalf, that person will be asked to sign the declaration.

In cases where a donor is physically unable to sign the form, the Independent Assessor will mark the form on the donor's behalf once the donor has indicated that they have read and understood the declaration. The Independent Assessor will explain this in their report to us.

In the case of an emergency liver transplant, a signed declaration must be provided by the living donor to the Independent Assessor. The Independent Assessor's report will tell us that they had received a declaration.

## **What if I do not want to sign the declaration?**

If you do not sign the declaration, this may affect our decision to approve the donation. However, we will not automatically turn the case down. The Independent Assessor will ask you to explain your reasons for not signing the declaration. This explanation will then be given in the Independent Assessor's report to us.

## **What happens after the interview with the Independent Assessor?**

The Independent Assessor will send us a report of the interviews with you and the recipient. We will then make a decision based on the contents of the report.

Once we have made a decision on your case, the Living Donor Coordinator will tell you whether the donation has been approved and can go ahead.

The table below provides a quick reference guide to approval procedures for different types of donation.

		HTA Independent Assessment interview needed	Signed declaration needed	Case considered by:
<b>Non-directed altruistic donation</b>	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority panel</b>
	<b>Recipient</b>	No	No	
<b>Directed altruistic donation</b> (no pre-existing genetic or emotional relationship)	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority panel</b>
	<b>Recipient</b>	Yes	No	
<b>Directed donation of a kidney</b> (there is a pre-existing genetic or emotional relationship)	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority living donation assessment team</b> (We may refer these cases to the panel for a decision.)
	<b>Recipient</b>	Yes	No	
<b>Paired / pooled donation</b>	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority panel</b>
	<b>Recipient</b>	Yes	No	
<b>Directed donation of adult to adult</b> (liver lobe)	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority panel</b>
	<b>Recipient</b>	Yes	No	
<b>Directed donation of adult to child</b> (liver lobe)	<b>Donor</b>	Yes	Yes	<b>Human Tissue Authority living donation assessment team</b> (We may refer these cases to the panel for a decision.)
	<b>Recipient</b>	Yes	No	

For more information about us please visit [www.hta.gov.uk](http://www.hta.gov.uk) or contact:

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