Tissue sample donation - Basic terminology & principles:

During medical treatment patients may be asked if they are willing to donate samples for research. The information that is given to help may be confusing at first and patients may want some time to think it over. Donating samples for research is entirely voluntary and refusing will not affect a patients treatment in any way.

Access to samples from patients is essential for the development of new ways of diagnosing and treating rare cancers such as GIST.

Samples:

Samples come in many forms, including:

- Blood
- Small bits of material ("tissue") left over after an operation or a test
- Whole organs or bodies

Consent:

Patient consent is usually required before samples can be taken for research.

Making sure consent is fully informed - Consenting before donating samples

Patients have the right to determine what happens to their bodies so it is essential to give consent before donating samples for research.

Consent is an important part of everyday life and in most cases, it is an informal process. For example, if you go to the hairdresser you consent to having your hair cut without having to sign a form. Consent in this case is given by your actions – going to the salon, sitting in the chair, moving your head to make the task easier. If a stranger sits behind you on the bus and cuts off your hair without your permission this would count as a serious assault!

Consent for the donation of samples for medical research is more formal. The person asking for consent has to provide sufficient information for a patient to make up their mind, in other words consent has to be "fully informed". In some forms of medical research the amount of information needed to meet the requirement for fully informed consent is very large – for example if you are being asked to take part in a drug trial. For the donation of samples, the list is not so long but there are still several topics which need to be covered.

Medical research:

Using human samples includes a huge range of methods including, in some cases, genetic analysis or the use of laboratory animals. Research may take place in Universities, other non-profit organisations or commercial organisations such as drug companies. These may be based in the UK or sometimes abroad.

Biobank:

A biobank is a collection of samples used for research.

In the UK research biobanks must hold a licence from the Human Tissue Authority to ensure that they have valid consent in place for the collection of samples and that storage facilities are of a good standard.

The use of samples is overseen by the Health Research Authority. A biobank may apply to have Research Ethics Committee (REC) approval for their collection, allowing them to

distribute samples without additional external review, as long as they keep within the scope approved by the REC and submit an annual report which describes how the quality of each application to use samples was assessed. The HRA has published a list of REC approved biobanks.

The value of patient tissue samples for research is greatly increased if it is accompanied by data. This may include, for example, age, gender and details of any medical conditions and how well the patient is in the time after samples are was taken. In most cases this is now held on computers, which can raise concerns about how securely it is kept. Retention of records which provide patient identity is very strictly controlled through the Data Protection Act (more details are given on the website of the Information Commissioners Office). In addition, researchers must comply with the Caldicott Guidelines which restrict information on a strict "need to-know" basis. In almost all cases there is no need for the researcher to know a patients name or where they live. These details may be retained by someone independent of the researcher so that additional information can be provided at a future date by, for example, looking at your medical records. This arrangement is called linked anonymisation. Linked anonymisation is also essential if a patient wants a sample to be destroyed if they decide to withdraw consent.

On occasions research will find something which could have an impact on a patient's health or that of their family. This is most likely to happen when the research involves a study of DNA- the body's genetic code. This may show an increased risk of cancer, for example. As half a person's DNA is passed on to their children this may affect their risk of cancer as well. It is very difficult to know how to deal with this in the best way and no solution is perfect!

One compromise is to:

• indicate roughly how likely it is that the research will throw up something unexpected. If, for example, the research involves normal DNA then incidental findings (as they are called) are more likely to occur than in studies where DNA is not studied

• inform that if something is found a GP or hospital doctor will be told so that they can decide whether the risk is sufficient to warrant asking a patient to repeat the test (this will need to happen in any event as the test will need to be done in a hospital laboratory). Before this happens, a patient may be offered expert genetic councelling so that you can understand the implications for their family.

Some biobanks will decide that they will not return findings to donors or the doctors looking after them as they take the view that the results are not sufficiently reliable to guide treatment and may cause unnecessary anxiety

Samples may be used in many different research projects and may also be requested for specific research projects and as part of drug trials. Information regarding a patient's donation should be available when they are asked for their consent.

Contact

If you are preparing for a GIST operation and your GIST type is not exon 11 mutation, please get in touch with The National GIST tissue bank today to ask about donating a sample for research ***gistbiobank@rmh.nhs.uk***

FAQ about giving and use of samples:

The responsibility for reviewing most proposals to collect samples from patients in the NHS lies with the National Research Ethics Service run by the Health Research Authority.

Researchers complete a application form where they set out why they want to collect samples, how they will do it and what the samples will be used for. They also submit copies of the patient information leaflet and consent form that they plan to use.

Applications are considered by a Research Ethics Committee (REC) including independent experts and members of the general public.

The collection of samples from NHS patients cannot start until the research team have REC approval and the go-ahead from the relevant hospital or GP clinic.

Although it isn't a legal requirement to sign a consent form to donate samples for research in most cases a patient will be asked to do this- as a record that they have understood what is involved and agree to the sample being collected and used in the way described in a patient information leaflet that they will be given to read.

Time should be given to read both the information leaflet and consent form carefully and there should be the opportunity to ask questions. This can pose practical problems in busy clinics and on a hospital ward.

A patient may be anxious about their treatment and there may not be time for to think everything through. If this is the case the patient has the option to say no-and this will not affect their treatment- or ask to take the information away to read later.

In some cases. the information will be available for a patient to go back and review later on-line. Remember, a patient can withdraw consent if they change their mind.