



Information leaflet for parents/guardians of patients under 16

USING SAMPLES FOR RESEARCH INTO GASTRO- INTESTINAL STROMAL TUMOURS (GIST)

Although there have been great advances in our understanding of cancer over the last 20 to 30 years, progress in some types of tumours has been slow because they are rare and it is difficult for scientists to find enough cases to study in detail. Only about 900 cases of Gastro-intestinal stromal tumour (GIST) occur each year in the UK so it is vital that we work together to improve treatment for this type of cancer.

As the parent of a child who may have, or has been, diagnosed with a GIST you have been approached as someone who may wish to support medical research by allowing the donation of a sample left over after your child's doctors have completed the tests they need to undertake as part of their diagnosis or treatment. Normally this material is discarded.

This leaflet explains why these samples are valuable for research into GISTs and what will happen to them if you decide to donate them to us.

It will give you more information about the use of samples for research and describes our policy for the safe keeping of tissue gifted in this way.

We would like to make it absolutely clear that making a donation of this type is entirely voluntary and if you choose not to donate this will not affect your child's care in any way.

Approval to undertake this research has been given by an independent NHS Research Ethics Committee (NRES Committee North East - Newcastle & North Tyneside 1)

Why are you are approaching me now?

Your child will soon be or has already have given a sample of blood, or other fluid or solid tissue to confirm your diagnosis or to contribute to your treatment. Once his/her diagnosis has been made, the remaining samples are very valuable for medical research.

We are therefore asking for your consent to allow use of any remaining samples for research, by giving it to the Biobank we have set up at the Royal Marsden Hospital, London. (A "Biobank" is a collection of samples used for research).

WHAT KINDS OF SAMPLES ARE YOU INTERESTED IN COLLECTING?

Many different kinds of sample are of value in medical research, including blood and small bits of "tissue" left over after your child's doctors have completed their tests after a biopsy or operation. ("Tissue" is the scientific name for a lump of cells- for example a bit of skin, bowel or kidney).

WILL YOU TAKE ANY EXTRA SAMPLES?

With the exception of a small volume (about a tablespoon full) of extra blood taken at the same time as taking a sample as part of your child's routine care, or some cells which we may gently scrape from the inside of their cheek with a cotton wool bud, NO extra samples will be taken as part of this research.

WHAT SORT OF RESEARCH WILL BE UNDERTAKEN USING MY CHILD'S SAMPLE?

Even very small samples are of great value for scientists trying to find out the cause of GIST or to identify new treatments. The methods they use include examination under a microscope and breaking the sample up to measure the molecules it is made of. This often involves a detailed analysis of the DNA in the sample. This is the "genetic code" which contains very useful information about the way in which diseases may occur or how treatments can be improved. Your child's DNA will not be used for any other purposes other than for approved medical research.

Some of our research may involve the administration of samples into rodents (rats or mice). This is only done when we want to understand more about the way in which a disease develops or responds to treatment. These experiments are performed according to the strict guidelines set out by the Government and involve the minimum of distress to the rodents used.

If you or your child do not wish to allow your child's sample to be used in this way then you can still agree to donation of your child's sample but please tell us if you don't want it to be used in research using animals.

WHERE WILL MY CHILD'S SAMPLE GO AFTER IT HAS BEEN DONATED?

If you agree to the donation of a sample for research it will either be used immediately as part of an approved project or stored in a secure room in the Royal Marsden Hospital, London, as part of the GIST Biobank.

Researchers based anywhere in the UK or the rest of the world will be able to apply to use samples for medical research but samples will only be sent to researchers for studies that have been approved after expert review of the research they plan to undertake. Samples will only be used for medical research. You can indicate on the consent form if you do not wish samples to be sent abroad. Research may be undertaken in Universities, research institutes or privately funded laboratories.

The biobank may charge researchers to obtain samples from the bank. This is in order to cover our costs rather than to make a profit.

Any additional money raised from sending samples to commercial laboratories will be re-invested in research or patient care. Under UK law sample donors are not entitled to a share of any profits which may result from this activity. You may indicate on the consent form if you do not want your child's sample to be used by commercial companies. Any sample left over after the research has been completed will be destroyed.

WHAT ABOUT MY CHILD'S PRIVACY?

We take your child's right to privacy very seriously. The value of samples taken for research is greatly increased by linking them to clinical records but this will only be done by NHS staff or those with an honorary contract requires that they adhere to the same rules regarding confidentiality that apply to your child's clinical care.

The research will be conducted anonymously, which means that your child's sample will be identified only by a code; your personal details will not be passed on to researchers. The researcher may be given your age, gender and details about the type of GIST tumour that he/she has alongside information about how he/she has responded to treatment.

Any information regarding your child's identity will be removed from the sample and will not be passed on to the researcher but will be kept securely by the biobank so that we can show that you have given informed consent and in case we have to contact your child's doctor about any findings which may affect their treatment. We will not keep details of your address or phone number.

Data will be kept in accordance with NHS security guidelines. Access to this data will be strictly limited on a "need to know" basis. It may be necessary for regulatory officials to check your child's medical records and laboratory data, to ensure that research is being carried out properly and in line with regulatory guidelines.

Will agreeing to donate my child's tissue affect his/her treatment?

Your child's diagnosis or treatment will not be affected in any way by providing blood or tissue for research. Any research studies in which your child's sample is used will have been approved by independent experts. This is to ensure that the research is justified and meets current ethical standards.

WHAT HAPPENS IF YOU FIND OUT SOMETHING WHICH MAY AFFECT MY CHILD'S FUTURE HEALTH- OR THAT OF MY FAMILY?

If research tests indicate something which may affect your child's future health or that of your family, we will discuss this with the consultant in charge of your case to decide if the test has a major impact on your child's treatment. If so, you will be informed of the results.

This will not be done by the research team which ,will not have your child's personal details, but through staff who work for the NHS or who have an honorary contract which requires them to maintain your child's confidentiality. If you do not want this to happen then please indicate this on the consent form you will be asked to complete.

In some cases, the result of tests carried out on your child's sample may indicate that your he/she could be eligible to take part in a clinical trial. If this happens then we may contact you to discuss this further. If you do not want us to do this then please indicate this on the consent form.

WHAT HAPPENS IF I CHANGE MY MIND?

You can change your mind about allowing samples to be retained for research at any time in the future- without giving any reasons- by contacting the GIST biobank manager (contact details below). Any samples remaining in the bank will be destroyed and any researchers to whom samples have been sent will be contacted and instructed to destroy any samples they have in their laboratories. It will not be possible to withdraw any data or findings from research work already undertaken using the donated tissue. However, if you withdraw consent we will remove all data that we can from our records.

WHERE CAN I FIND OUT MORE?

If you are giving consent to the donation of your child's tissue in a clinic or hospital you can discuss any issues raised in this leaflet with the member of staff who will be taking your consent for samples to be stored for research.

If you are being asked to give your consent before your child goes in to hospital and therefore do not have the chance to discuss any concerns you may have in person, then you can contact the GIST biobank by e-mail gistbiobank@rmh.nhs.uk or phone 0207 811 8395. They will be happy to answer any questions that you may have.

You can also find further information on the GIST Support UK web site (<http://www.gistsupportuk.com/humantissue.htm>)

WHAT HAPPENS NEXT?

If you are interested in donating your child's sample for GIST research please read through and sign the consent form sent or given to you with this information leaflet. Please remember that we will be happy to answer any questions that you may have by e-mail or phone, using the contact details given above.

Please remember- donation is entirely voluntary and if you decide not to donate will not affect your child's treatment or diagnosis in any way.

Thank you