



## **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 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 Biobank manager by e-mail E-mail [janine.salter@rmh.nhs.uk](mailto:janine.salter@rmh.nhs.uk) or phone 0208642 6011). She, or one of her colleagues 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**

## **CONSENT FOR GIFTING OF CLINICAL SAMPLES: PARENTS/GUARDIANS OF PATIENTS UNDER 16**

**Title of Project:** Use of Diagnostic Samples and Samples Taken During Therapy to Support Medical Research – to be stored in the GIST Biobank at the Royal Marsden Hospital, London

**Name of Researcher:** Dr Robin Jones on behalf of the GIST Biobank

### **Why am I being approached?**

Your child will shortly be giving a sample of blood, or other fluid or solid tissue to confirm their diagnosis or to contribute to their treatment. Once the diagnosis has been made the remaining samples are very valuable for medical research. We therefore ask for your consent to allow use of any remaining sample 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). A leaflet has been provided to you containing more information about the use of samples for research and describing our policy for the safe keeping of tissue gifted in this way.

### **Will any extra samples be taken?**

You may be asked for permission for your child to donate a small volume of extra blood (up to about 1 tablespoonful), taken at the same time as sample is being taken as part of their treatment or we may ask if we can gently scrape some cells from the inside of their cheek using a soft cotton-wool bud. No other additional samples will be taken.

### **Will this affect my child’s treatment?**

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

### **Will my child be identified?**

The research will be conducted anonymously, which means that your child’s samples will be identified only by a code, rather than their name when they are passed on to a research team. Apart from their age, and gender and details of their response to treatment, their personal details will not be passed on to researchers. We will retain records of their name and hospital number so that we can contact their doctor in case we find a result which could affect their treatment. We will not retain your address or other personal contact details. Their confidentiality will be respected at all times.

It may be necessary to gather information from your child’s medical record that is relevant to the research being conducted, such as the type of treatment they are receiving. This will only be done by a member of their healthcare team, or by someone that has a confidentiality agreement with the NHS. It may also be necessary for regulatory officials to check their medical records and laboratory data, to ensure that research is being carried out properly and in line with regulatory guidelines.

### **What will happen to my child’s samples?**

Samples donated to the Biobank will be used by research teams both in the UK and elsewhere, including other countries such as mainland Europe and the USA. If you do not wish your child’s samples to leave the country you can indicate this on the form we ask you to sign. Samples will only be used for medical research. Some of the research may involve the administration of samples into rodents (rats or mice). This is only done when it is essential to further our understanding of 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 do not wish to allow your child's samples to be used in research using animals then please indicate below.

Some research may include testing your DNA. Researchers will not know your child's identity and their samples will only be identified by an anonymised code. Their DNA will not be used for any other purposes other than approved medical research.

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.

We may use the samples in association with commercial partners, such as pharmaceutical companies. Any resulting benefits from these partnerships will be used directly to improve patient care or to enable us to perform more research. Although the research will not be conducted for the purposes of making money it is possible that some of the results, once published, will be of value to commercial companies, for example in the development of new tests or treatments.

### **Are there any restrictions on how my samples will be used?**

We will only use your donated samples for studies that have been approved after expert review.

Use of your tissue or cells for research in this way will not directly influence your child's treatment. If research tests indicate something which may affect their future health or that of your family we will discuss this with the consultant in charge of their case to decide if the test has a major impact on their treatment. If so you will be informed of the results. If you do not wish this to happen then please indicate below.

Tests performed on your child's sample may indicate that they are eligible to take part in a clinical trial. If this is the case we may contact you to discuss this further. If you do not want to be contacted in this way in the future please indicate below.

**Withholding consent will not affect the diagnosis or treatment of your child in any way. If you do not wish to give consent, we guarantee that any sample surplus to the needs for diagnosis is disposed of appropriately, following national guidelines.**

The parent or guardian should complete the whole of this sheet himself/herself

**Please INITIAL (rather than tick) each section to indicate your approval and strike out any section which you do NOT approve. If you have any questions please either discuss these with the person taking the consent (if done in person) or contact the GIST biobank by e-mail or phone**

I agree to the use of my child's sample(s) after diagnosis for research

If **yes** please answer ALL the following questions:

|   |  |
|---|--|
| Have you read and understood the patient information sheet?<br>(Please take a copy home with you to keep)   |  |
| Have you had an opportunity to discuss the Biobank and ask any questions either in person or by phone or e-mail with biobank staff?   |  |
| Do you understand that you are free to withdraw your consent from the Biobank at any time without having to give a reason and without affecting your future medical care?   |  |
| Do you agree to donate samples in excess of what is required for medical purposes and for these to be used immediately or stored for future use in approved research projects?  |  |
| Do you agree to an extra volume of blood (up to 1 tablespoonful) to be taken for research at the same time as your child has a sample taken as part of your routine care?   |  |
| If requested, do you agree to having cells scraped gently from the inside of your child's cheek, using a soft cotton-wool bud?  |  |
| Do you understand that you will not be told the results of any tests which may be carried out on your child's samples unless there is a test which might be useful to your child, in which case your child's doctor will be contacted?  |  |
| If research undertaken using the sample indicates that there is a test which may influence your child's treatment or the health of your family, do you give permission for your doctor to be approached to discuss the best course of action?   |  |
| If research undertaken using the sample indicates that there is a test which would make your child eligible for a clinical trial, do you give permission to be contacted by a member of the relevant research team to discuss this further?   |  |
| Do you give permission for your child's DNA to be tested for the purposes of research?  |  |
| Do you give permission for your child's medical information to be stored?   |  |
| Do you understand that relevant sections of your child's medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to them taking part in this research? Do you give permission for these individuals to have access to your child's records? |  |
| Do you give permission for your child's samples to be used in experiments using rodents (rats or mice)?   |  |

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|--|--|
| Do you give permission for samples to be used by commercial partners (for example drug companies)? |  |
| Do you give permission for samples to be sent to centres outside the UK?                           |  |

|                                     |      |           |
|-------------------------------------|------|-----------|
| Patient (& Hospital number)         | Date | Signature |
| Person taking consent (if relevant) | Date | Signature |

3 Copies: 1 for patient, 1 for Biobank and 1 to be kept with hospital notes

**Contact Details:**

Dr Robin Jones, Chief Investigator robin.jones4@nhs.net