

## NATIONAL GIST BIOBANK

### 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:** Prof Robin Jones on behalf of the National 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? (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 GIST 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)?	

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  
**Once completed:** Please send scanned consent form to [gistbiobank@rmh.nhs.uk](mailto:gistbiobank@rmh.nhs.uk)

**Contact Details:**  
Prof Robin Jones, Chief Investigator  
Email: [gistbiobank@rmh.nhs.uk](mailto:gistbiobank@rmh.nhs.uk)  
Telephone: 0207 811 8395