

NATIONAL GIST BIOBANK

CONSENT FOR GIFTING OF CLINICAL SAMPLES: PATIENTS OVER 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?

You will shortly be giving a sample of blood, or other fluid or solid tissue to confirm your diagnosis or to contribute to your treatment. Once your 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 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 your treatment or we may ask if we can gently scrape some cells from the inside of your cheek using a soft cotton-wool bud. No other additional samples will be taken.

Will this affect my treatment?

Your diagnosis or treatment will not be affected in any way by providing blood or tissue for research. Any research studies in which your 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 I be identified?

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

It may be necessary to gather information from your medical record that is relevant to the research being conducted, such as the type of treatment you are receiving. This will only be done by a member of your healthcare team, or by someone that has a confidentiality agreement with the NHS. It may also be necessary for regulatory officials to check your 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 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 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 samples to be used in research using animals then please indicate below.

Some research may include testing your DNA. Researchers will not know your identity and your samples will only be identified by an anonymised code. Your 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 treatment. If research tests indicate something which may affect your 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 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 you sample may indicate that you 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 your diagnosis or treatment in any way. If you do not wish to give consent, we guarantee that any sample surplus to needs for diagnosis is disposed of appropriately, following national guidelines.

The donor 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 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 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 you have a sample taken as part of your routine care?	
If requested do you agree to having cells scraped gently from the inside of your 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 samples unless there is a test which might be useful to you, in which case your doctor will be contacted?	
If research indicates that there is a test which may influence your 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 indicates that there is a test which would make you 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 DNA to be tested for the purposes of research?	
Do you give permission for your medical information to be stored	
Do you understand that relevant sections of your 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 you taking part in this research? Do you give permission for these individuals to have access to your records?	
Do you give permission for your 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 Name (& Hospital number)	Date	Signature
Name of person taking consent	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

Contact Details:
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