PARTICIPANT INFORMATION SHEET
STUDIES ON ISOLATED TISSUES TO INVESTIGATE NEW MEDICINES

You are being invited to take part in a tissue collection project for medical research. You do not have to take part if you do not wish to. Before you decide whether you will or not, it is important for you to understand why the project is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with your friends or relatives if you wish. Please ask the medical and donation centre staff about anything that is not clear or if you would like more information.
Thank you for taking the time to decide if you wish to participate in this study.

Purpose of the Research

Human tissues play a critical role in medical research. They are vital in helping us to understand the complex processes of human disease and how we can improve treatment options.
Medical research can take many forms and use many different laboratory techniques. For example, researchers can measure levels of protein and other biomarkers, how a muscle tissue contracts, or how molecules move through a tissue. Tissue can also be used to create cell lines which can be grown and used for several months or years in the laboratory. Such cell lines can be composed of different cell types (e.g., skin cells) and can be treated to make a different cell type (e.g., stem cells). Some cell types can also be treated so that they do not die as normal but instead are able to grow indefinitely – these are called immortalised cell lines – and can be grown and used in the laboratory for many years. These types of study and laboratory techniques are used to investigate how a disease begins and progresses, how we can identify and treat the disease, and, in some cases, they can be used to help design and improve available treatments.
To help with this type of research, biospecimens, such as, blood, urine, stool, sputum, nasal, and skin samples are required from both healthy and patient volunteers. We would like to collect, store, and use some of your tissue, and your clinical information, for medical research that aims to design, develop, and improve new drugs to treat disease.

Why have I been chosen?

You have been invited because you have a medical condition of interest for this project, or because you do not have a medical condition and are considered “healthy” or “disease free”.

Do I have to take part?

No. It is entirely up to you to decide if you want to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. The consent form does not take away any of your rights but ensures that you have been fully informed about the project. You can decide which types of biospecimen you are willing to donate, for example you may only wish to donate blood. Staff will advise what the specific requirements are for the project. If you decide that you would like to take part, you are still free to withdraw at any time and without giving a reason. This will not affect your medical care in any way nor prevent you for volunteering for studies in the

future. Please ask the donation centre staff if you have any unanswered questions to help you make an informed decision.

What will my taking part involve?

The first thing you need to do is give your written permission (consent) by signing the form attached to this leaflet. This may occur before or at the same time of providing a biospecimen. You will consent to only those biospecimen types that you are willing to provide.

In some instances, you may be asked to provide an additional small blood sample or other biospecimen type, to determine if you are suitable for the project. This may include testing your sample for viruses such as HIV, hepatitis B/C or SARS-CoV-2. Staff will advise if this is a requirement and provide you with information on these tests. An additional visit to the donation centre may be needed to perform these tests and they would only be performed with your consent.

Dependent on the project requirements, you may be asked to attend the donation centre to provide a single biospecimen donation or to donate on multiple occasions. You may also be asked if photographs can be taken of the area to be sampled, for example, an area of diseased skin before a skin biopsy procedure. Any photographs taken will only be of the area being sampled and will not identify you in any way. Staff will advise on the requirements when discussing the project with you.

Before donation, you will be asked about any medical conditions and medications that could affect your ability to provide a biospecimen. Staff will assess if you should continue to biospecimen donation, and you will only continue to donation if it is considered safe for you to do so.

Blood donation: A small finger pinprick test may be performed on the day to ensure that you are able to donate safely. A blood sample will be taken from a vein in your arm by an experienced member of staff. No more than 60 mls (3-4 tablespoons) will be taken. You may be asked to make more than one donation at various time intervals. If asked to do this, no more than 60 mls will be taken at each visit, and no more than the recommended volume (470 mls) in any 12-week period for males or 16-week period for females.

Urine and stool (faecal) samples: You may be asked to provide a single urine or stool sample or to collect samples over a period of time. Instructions will be provided by staff on when and how to collect, and whether the collections can be performed at home or at the donation centre.

Sputum samples: You may be asked to produce a spontaneous sputum (phlegm) sample in which you would naturally cough up your sputum from your chest into a container provided by staff.

Nasal samples: You may be asked to provide a nasal sample. This may be a nasal wash, brush, or swab. For each type, you will be asked to sit and extend your head to the best position for sampling. For the wash, your nose will be flushed with a sterile solution and the wash collected. For the brush, a plastic sterile scope and a speculum instrument will be used to open your nasal cavity and the brush

inserted to brush the nasal cell lining. For the swab, a sterile swab will be inserted and rubbed against the side of the nose. Each type of nasal procedure will take approximately 5 minutes to perform.

Dermatological (skin) samples: You may be asked to provide a skin biopsy or skin tape strips.
Skin biopsy. A skin biopsy is a procedure that removes a piece of skin from your body. This procedure can be performed in different ways – we will use the punch biopsy technique which allows very small sections of skin tissue to be taken. The procedure will be performed by an experienced member of medical staff. A local anaesthetic will be applied to numb the area of skin to be biopsied. A small instrument similar to an apple corer, called a punch, will be used to take a small 3-4 mm skin punch biopsy sample. The punch is placed over the area to be biopsied and pushed down firmly to take the sample. You may feel some pressure during the procedure but no pain. Sterile strips or stitches may be used to close the wound and advice will be provided if stitch removal post procedure is required. Once the anaesthetic has worn off, the sampled area may be painful. Paracetamol should be sufficient to ease this pain. A maximum of 3 (each 3-4 mm) skin punch biopsies may be taken at one visit and the procedure should take around 30 minutes.
Skin tape strip. Tape stripping is a simple non-surgical method to remove the top layer of skin only. Special sticky tape is applied to the skin and pressure applied for a short time – usually 10-20 sec. The tape is then removed in a single movement. The tape is applied several times to a single area to ensure that the top layer of skin is removed. You may feel a little discomfort as the tape is removed – similar to removing a plaster. Up to 5 different skin areas may be sampled at one visit.
Biopsy and tape strip samples will be taken from areas of skin affected by a skin condition and/or from a section that is unaffected – usually from the arm, leg, stomach, or back areas. This allows researchers to investigate if there are any differences in how healthy and damaged skin respond to a treatment. Medical staff will discuss with you the best areas of skin to sample. If there is an area of skin that you would prefer not to be sampled, please let the medical staff know.

The processes involved in taking any biospecimen will be explained fully by staff at the donation centre.

What are the risks to you?

The risks when giving blood are small. You may feel slight discomfort when the needle is inserted into your vein, and in some cases a small bruise may develop. The amount of blood taken does not place you at any risk.

Nasal samplings are simple, non-invasive procedures that may cause minimal discomfort during the sampling process. You may be advised by the medical team not to donate if you suffer from nasal problems, for example, frequent nose bleeds.

No risks are associated with tape stripping the top layer of skin. The procedure is non-invasive and causes only mild discomfort. A red mark may be seen but this is temporary and will disappear shortly after the procedure.

The skin biopsy procedure is a small surgical procedure, generally safe and with minimal risk. Complications are rare but can occur. You may experience some minor bleeding, minor scarring, infection, or an allergic reaction. Any bleeding that you experience will be stopped by the medic before leaving the clinic. You will be given direction on keeping the wound clean and provided with dressings to minimise infection. If you suffer from a bleeding disorder, are taking blood thinning medication (such as aspirin or warfarin), have a history of skin infection, or have a known allergy to rubber gloves, dressings, or antiseptic solutions, you should let staff know at the time of the procedure. It is impossible to cut skin without leaving a small fine scar; in most cases this will be the case, however, the scar can be more pronounced in some individuals.

Are there any restrictions?

Depending on the project requirements there may be certain restrictions such as avoiding smoking, alcohol, caffeine, certain medications, or strenuous exercise before donation. You may be required to fast overnight e.g., not eat or drink except for water. You will be advised of these restrictions by staff at the donation centre.

Will my taking part in this research be kept confidential?

Staff may ask you some questions about yourself and your current or past health. You may be asked to allow them to look at your personal medical records to obtain this information. This clinical information will help researchers to interpret the results of the work they undertake. Information will be coded by the donation centre team before it is given to researchers.

We are legally obliged to maintain the highest level of confidentiality with all personal information so that others cannot identify you. The donation centre staff will take every security precaution to prevent researchers from obtaining any information that could identify you. The only people who will know your identify will be the health care team at the donation centre who are bound by a professional duty to protect your privacy. Researchers will NOT be provided with any identifiable personal information and will NOT be able to contact you directly. Researchers will be bound by a strict legal agreement to ensure this.

Will my sample be used in genetic research?

Researchers may test for inherited genetic disorders. An inherited genetic disorder can pass from parent to child. Researchers may also investigate genetic material (genes) associated with disease and how our genes can be used to predict response to drug treatment. The researchers will only have a code number for your tissue. The results of these genetic tests will not be traced back to you. Researchers will only use the results of their tests for medical research and teaching purposes. Any possibility of being able to identify you from your genetic material, now or in the future, will be very small.

What expenses or compensation will I receive for taking part?

A payment in the region of £40-£200 will be made per procedure depending on which procedure(s) is/are required. This is paid on completion of each study visit to compensate for any inconvenience caused by your participation. You will also be reimbursed for any travel expenses necessary to attend the clinic on the day of donation. You will be advised of the payment schedule before attending for the visit.

What will happen if you say no?

You are free to say no – the choice is yours. Your decision will NOT affect the standard or type of care you will receive from medical staff, now or in the future. If you say no, we will not take any samples from you nor will we collect any information.

What happens if you change your mind?

You can change your mind at any time by contacting the donation centre. You do not need to say why you have changed your mind. The donation centre will then contact the researcher and all relevant tissue samples in storage will be destroyed. Similarly, the information stored about you will be deleted.

You can decide the type of sample that you wish to donate. You can change your mind about which samples types you wish to donate. Just let the study team know and a new consent form can be prepared.

If you change your mind after a long time, the samples may have already been used. The donation centre cannot recall samples or information from researchers once they have been used. However, they will request the disposal of any original biospecimens that remain so that your sample will not be used in any further research.

What are the benefits to you?

This is laboratory research, and although your participation will not provide any direct medical benefit to you, the results will be valuable in furthering medical research or the development of medicines and treatments of potential benefit to others. There will be no financial benefit for yourself from the development of any new treatments.

Research use of the specimens/samples may result in commercial gain, patents may be filed, and research results commercialised. You should not expect to benefit directly from any commercialisation.

What happens if something goes wrong?

The collection of biospecimens will be done by an experienced professional at the donation centre and following all approved processes and protocols. If you wish to complain or have any concerns about any aspect of the way you have been approached or the biospecimen collection process, then please contact [insert details for donation site].

In the event that something goes wrong, and you are harmed during donation, and this is due to someone's negligence, you may have grounds for legal action; however, you may have to cover all costs for this.

Who is organising and funding the research?

REPROCELL Europe Limited is organising and funding the research. REPROCELL Europe Limited is a Contract Research Organisation with ethically approved Research Tissue Bank status. This allows REPROCELL to act as custodians of samples it holds and to release samples, including cells, to individuals or organisations, both in the UK and abroad, that meet acceptable scientific criteria and work to the highest ethical standards.

Other things you should consider

The biospecimen and information you donate may be made available to researchers in the UK or overseas. They may work in universities, hospitals or in private/commercial companies that perform medical research.

Your donation will be used for human medical/biological research and will not be provided for any other purpose. This research will always be relevant to understanding how the body works and responds, which may eventually help researchers to understand and treat a range of disorders.

The biospecimens you have donated will never be sold for profit; however, private/commercial companies may make a profit on the creation and use of cells, the generation of data or development of new medicines, arising from the biospecimens you have donated.

Contacts for further information

If you have any questions or concerns about the donation of samples and information or the possible uses of them, please speak to the person discussing donation with you in the first instance. Help with your questions and concerns can also be obtained by contacting the:

Local Study Manager: ☎ ✉ (Insert site specific information)

or

REPROCELL Clinical Alliances Manager: ✉ clinical.allainces@reprocell.com

You can also find more information about the type of research that will be performed by visiting the REPROCELL Europe Limited website www.reprocell.com or about tissue donation for research in general from the Human Tissue Authority website www.hta.gov.uk.