

Anonymization number (to be completed by the collecting organization):

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**CTiBiotech, CELLULAR THERAPY RESEARCH INSTITUTE**

Building A16, 5 Avenue Lionel TERRAY, 69330 MEYZIEU-LYON, FRANCE Tel: 09.67.10.74.55 /

[office@ctibiotech.com](mailto:office@ctibiotech.com)

Approval number from the Ministry of Higher Education, Research and Innovation:

AC-2023-5886; DC-2023-5900; IE-2020-1119

Mrs Miss Mr,

We invite you to participate in scientific research and advance scientific knowledge through your donation of a skin sample for research. The objective of this document is to provide you with all the necessary information so that you can understand the purpose and constraints of your donation.

Do not hesitate to ask your biologist or health professional for an explanation of words or expressions that you do not understand.

**THE OBJECTIVE OF THE RESEARCH**

We use your skin samples from surgery (skin) for basic research purposes but also for public health purposes for the development of products intended to be placed on the market. Scientific research may be carried out either by us or by other companies or institutions. Donating your sample also helps reduce the use of laboratory animals.

**LEGAL AUTHORIZATIONS**

CTiBiotech has dual accreditation (reference AC-2018-3243 and DC-2018-3242) from the Ministry of Higher Education, Research and Innovation which authorizes the collection, conservation and preparation of tissues and cells of the human body for their transfer as part of a commercial activity, for scientific use (Application of articles L. 1243-3 and L. 1243-4 of the public health code). Article L. 1245-2, law of August 6, 2004, regulates the use of any biological material not used in the context of care, for scientific research purposes. This law provides that the donation must be made with strict respect for confidentiality, anonymously and free of charge.

**PROCESS OF THE RESEARCH**

During certain surgeries, excess tissue is sometimes removed by the surgeon. These tissues are usually destroyed.

After obtaining your agreement to participate, the surgeon will collect a fragment of tissue taken during the operation. The tissue collected will then be sent to CTIBiotech for its use for scientific purposes as previously specified.

### **INFORMATION ON POTENTIAL RISKS**

This donation does not carry any additional risk for your health. The examinations performed are perfectly known and mastered.

### **COSTS**

There is no additional cost regarding collection for research.

### **PROTECTION OF PATIENTS AND RIGHT OF WITHDRAWAL**

CONOFRANCE CTIBiotech has received authorization AC-2018-3243 and DC-2018-3243 allowing it to prepare and preserve samples and products derived from elements of the human body with a view to their use or transfer for scientific use as detailed in article L.1243-4.

Each sample is anonymized. A number is associated with each consent and it is impossible for us to know the identity of the donors. You will sign two copies, one for you and another for the sampling establishment which will be kept. We do not receive any copies.

You have the right to refuse to participate in this research or you can withdraw your consent at any time, without incurring any liability or prejudice as a result (Art.L.1122-1 of the Public Health Code). If you wish to withdraw from the study, please contact CTIBiotech (contact information located at the end of this form) by providing us with your anonymization number indicated on the consent form. Samples that have not been used and/or retained samples will be destroyed.

After you make your donation, you are allowed to participate in another trial.

The results of the examinations carried out as part of this study will not be communicated to you.

However, in the event of discovery of an anomaly in the samples, we communicate the results to the collecting establishment.

You can choose or not to be informed (see consent).

No compensation will be paid to donors for their participation in the study. All study participants will be affiliated to a social security scheme.

No research will be carried out on a person without their prior consent. Access to the information contained in the medical file is possible directly by the patient himself since Law No. 2002-303 of March 4, 2002.

At the end of the study, you will be able to receive information from the researcher in charge of this research regarding the overall results of this study.

## **COMPUTER AND FREEDOM**

Computerized processing of the data collected in this study will be carried out strictly ANONYMOUS (the data will be identified by a code number or anonymization number).

In order to protect individual freedoms, the law provides that: You have a right of access to the information concerning you contained in this computer file, and a right of rectification if necessary and the verification of their destruction at the end of the one-year period provided for in article R.2045.

This right of access to information concerning you is exercised either through a doctor of your choice or directly (this since the law of March 2002).

This right of access is exercised through your doctor, and any possible rectification will be made. within the business day of your request.

These data extracted from the computerized file will be used according to strict criteria. confidentiality, unless you object to the doctor at your diagnostic center.

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### CONSENT FORM

I, the undersigned, .....(First and last name)

Born on .....(date DD/MM/YYYY) in ..... (city),

residing at the following address: .....

.....

declares that I accept, freely and in an informed manner, to give my skin sample for scientific research, carried out by public or private institutions via the company CTIBiotech located at 5, avenue Lionel Terray 69330 MEYZIEU.

I confirm that I have been informed clearly and fairly and that I have received and understood all the information given to me. Additionally, I was provided with sufficient thinking time to review the information and had the opportunity to ask questions which were answered satisfactorily by the facility's medical staff.

#### Exceptional communication of analysis results of collected samples:

I agree that in the event of discovery of a result presenting an abnormal and serious risk to my health, during the research carried out using the sample, that this information will be brought to the attention of the health professional who carried out the procedure. at collection or from my attending physician. I am informed that the provision of this medical information is the responsibility of a healthcare professional (*and not CTIBiotech*). The health establishment will be responsible for carrying out additional analyzes and contacting me if necessary.

**Or**

I oppose the communication of such information to any health professional and wishes to remain in ignorance of this result.

Place : .....

date : .....

*"I hereby give my informed consent for the collection of blood for scientific purposes"*

*Signature*

#### People to contact if necessary:

- Managing Director: Dr Nico Forraz, Tel: 09 67 10 74 55
- Scientific Director: Prof Colin McGuckin, Tel: 09 67 10 74 55
- Email address: office@ctibiotech.com

The information collected via this form is subject to computer processing implemented by the health establishment. The recipients of this data are only the staff of the health establishment, subject to professional secrecy.