PATIENT INFORMATION SHEET

Study name: Genomics, Proteomics and Biomarker Research of Human Diseases

Dear Patient!

In collaboration with your hospital we are conducting "Genomics, Proteomics and Biomarker Research Study of Human Disorders" protocol. The purpose of this study is to collect and analyze patient biospecimens (surplus surgical tissue and/or biofluids such as blood, urine, saliva, sputum, bronchial lavage, buccal sells, etc.), your demographic and clinical data for biomedical research. Collected biospecimens will be utilized for identification of novel drug targets, biomarker discovery and development aiding the better drug efficacy and safety, creation of clinically-relevant diagnostic tests often specifically created for drug-targeted patient groups and other types of biomedical research. As a part of scientific analysis, we can perform genetic tests on your samples; including whole genome sequencing (complete sequence of your DNA containing the instructions for your body's development and function will be determined). We would like to use your specimens and data for the other research projects in the future, including future genetic research. Your data also may be shared with large online databases. Only qualified researchers, who have received prior approval from individuals that monitor the use of these data, will be able to look at your information.

Participation in this study is voluntary and you could withdraw from this study at any time.

No new drugs will be tested. You will not have any direct benefits from this study; however, the results may help developing new scientific knowledge and better treatment options and better diagnostics for patients in the future.

If you agree to participate in this study:

1. You will be asked some questions about your medical history.
2. You will be asked to give small samples of surplus surgical tissue and blood for research purposes. Personal information (name, date of birth, etc.) associated with these samples will be masked. The samples will be used for various tests for research purposes only, and may be stored for an unspecified period of time for future studies.

All information you give us will be treated strictly confidentially. No information will be published that might identify any participant. Participation in this research is optional and will not affect your treatment should you decide not to take part. You will not be financially compensated in any way (now or later) for your participation. If you are willing to help us, please read and sign the enclosed consent form (page 2).

.....
Name of the **Patient** (print in block letters)

Please tick appropriate box below.

☐ Yes, I am willing to take part in the "Cureline Genomics, Proteomics and Biomarker Research Study" as described. I allow my medical records and any other information relevant to my diagnosis to be released to properly qualified personnel (strictly confidential).

☐ Yes, I agree to donate the following human biospecimens (put initials to all that apply):

____	Blood		____	Surplus surgical tissue (tumor, other)
____	Urine		____	Buccal Cells (oral rinse)
____	Saliva		____	Skin punch biopsy
____	Sputum		____	Other specimen (specify)
____	BAL		____	I will not donate any human biospecimens at this time

....
Date (month/day/year) Signature of the **Patient**

PATIENT INFORMED CONSENT

Study name: Genomics, Proteomics and Biomarker Research of Human Diseases

.....

Name of the **Patient** (print in block letters)

1. I confirm that the nature, purpose, and possible side effects of the project have been explained to me, clearly and in detail, by the physician or another member of the project team:

....

Name of the **Medical Practitioner** (print) Name of the **Hospital / Institute** (print)

2. I received a copy of, have read and understood the content of the Patient Information sheet and the Informed Consent imprinted below. In addition, I had the opportunity to discuss the study operation with my Medical Practitioner. All my questions have been answered satisfactory.
3. I had enough time to decide whether I want to participate in the study or not, and I give a free consent to participating in the study as described in the Information sheet.
4. I understand that I am entitled to withdraw my consent whenever I want (verbally or in writing) without stating any reasons and without any disadvantageous consequences. If I withdraw my consent, my samples will be destroyed and further data analysis will be terminated; but I understand that any data that has already been shared may still be used, including information stored in electronic databases.
5. I understand that all tests shall serve only the research purposes. Although the project may advance medical knowledge and improve future treatments of human diseases, I may not experience any direct benefits by participating in this study: the results of the study may have no influence over my treatment options, and I will not receive the results of the research tests.
6. The study may lead to development of new laboratory tests and medications, which will be sold in the future. I understand that I shall not be entitled to know the research results obtained from my samples or to claim any resulting revenues. I understand that I will not receive any money for providing my biospecimens and that I will not be able to claim compensation, royalties or any other financial advantages or profits, which are potentially based on scientific results gained from research with my biospecimens.
7. I understand that all specimens collected for this study will be procured during my hospitalization of follow-up visits that are paid for by my insurance or by me.
8. In the event research results are published, neither my medical history nor my identity will be disclosed. The study protocols are kept in anonymous form. I agree to allow my data to be digitally saved and analyzed in applications for statistical purposes. For quality assurance purposes I agree that only authorized persons, who are also subject to medical confidentiality, may view my data for inspection and control. Furthermore, the applicable legal statutes pertaining to data privacy apply.
9. I understand that the content of the study is confidential and that I am not allowed to pass on any information to any other party except medical and scientific personnel involved in this study.
10. I agree to the transfer of my biospecimens to the sponsor of this study, and understand that they could also be used by the third parties, including international organizations.

....

Date (month/day/year) Signature of the **Patient**

To be completed by the physician responsible for the study:

I, _____ (name of the physician) have informed the patient named above of the purpose, nature, duration, and risks of the study, and confirm that he/she has given consent to participate in the study

....

Date (month/day/year) Signature of the **Principal Investigator**

CONSENT FOR DONATION OF ANATOMICAL GIFTS

SECTION I. LEGAL NEXT OF KIN

I, _____(name of the person signing the consent), the legal next of kin for_____(donor name , certify that my relationship to the donor is:

- ☐ Spouse (husband or wife)
- ☐ Parent (either one)
- ☐ Adult Brother or Sister
- ☐ Adult Grandchild
- ☐ Grandparent
- ☐ Guardian at Time of Death
- ☐ Other_____(specify)

I do hereby grant consent for donation of anatomical gifts with no notice that the donor, or family members of equal class to me, would oppose this gift.

SECTION II. INFORMATION ON DONATION AND USE OF DONATED TISSUES

1. The decision to donate is a private, voluntarily and confidential decision; no information will be released without your consent; no additional expenses will be incurred by you or the family.
2. The donated tissue will be recovered using surgical procedures by specially trained technicians. Only those tissues needed for research or education will be recovered, and it may include skin, bones, tendons, ligaments, muscle, nerves, blood vessels, fluids and other organs. Tissues donated for research may be as small as biopsy, or may include an entire organ or organ system depending on the organ size and /or researchers needs.
3. The donated tissue may be used for a broad range of non-profit and commercial **research purposes only**: scientific investigation, medical education, drug and diagnostics research and development for finding cures or treatments for human diseases.
4. To assure the safety of the tissue, I consent to the recovery of blood and tissues for laboratory testing that includes, but may not be limited to, blood typing, viral hepatitis, syphilis, and HIV.
5. I consent to allow obtaining donor's medical information, including, but not limited to, medical records, death certificates, or autopsy reports.
6. I understand that hospital personnel will be reimbursed for the work involved in the sample preparation, but I will not receive any payment for my gift. This consent is motivated by humanitarian considerations without the expectation of reward or compensation of any kind.
7. The gift may be used in various locations locally and internationally. The tissue and the information obtained may be released to different types of organizations for research use including hospitals, universities, and pharmaceutical or biotechnology companies.

8. I understand that I will not receive any results or medical information obtained from research or study of the donated tissues.
9. I release any and all claims that I may have as the authorizing person regarding the disposition of the donor's tissue.

Authorized Decision Maker (Print Name): _____

Authorized Decision Maker (Signature): _____

Date: _____

Relationship to Donor: _____

Address: _____

City: _____

Country and ZIP code: _____

Requestor (Print name): _____

Requestor (Signature): _____

Organization: _____

Title: _____

Date: _____

Witness (Print name): _____

Witness (Signature): _____

Date: _____