EXPECTED ELEMENTS IN THE INFORMATION SHEET FOR PARTICIPANTS - CNER template version from 07.03.2023

Date and Version number

**PARTICIPANT INFORMATION SHEET**

TITLE OF STUDY

CONTACT PERSON FOR FURTHER INFORMATIONS / if applicable contact details of the DPO

With the support of NAME OF SPONSOR(S)

You are invited to take part in a research study at our institution. This document is intended to better inform you, so that you can give your consent or refuse to participate in this study.

Your participation is entirely voluntary. You can withdraw from the study at any time without having to give an explanation. The withdrawal of your consent, as well as the refusal of your participation, will not involve any disadvantages for you and have no influence on your medical care and treatment. This study has received a favorable opinion from the National Research Ethics Committee.

**Objective and description of the study**

HERE, BRIEFLY DESCRIBE THE OBJECTIVES, EXPECTED BENEFITS, THE STUDY COURSE, ITS DURATION.

IF APPLICABLE, PLEASE SPECIFY:

- THAT A REMUNERATION IS FORESEEN FOR THE PERSON AND/OR THE INVESTIGATOR FOR THEIR PARTICIPATION

- THAT SECONDARY USE(S) OF SAMPLES AND/OR (CLINICAL) DATA IS/ARE CONSIDERED, AND THAT THE PERSON MAY CHOOSE TO CONSENT OR NOT TO THIS VIA THE SIGNATURE OF A DISTINCT INFORMED CONSENT FORM. SPECIFY THAT THESE SECONDARY STUDIES WILL BE SUBJECT TO OBTAINING A FAVORABLE OPINION FROM THE CNER

- THAT GENETIC ANALYSES ARE CONSIDERED IN ADDITION TO THE MAIN STUDY, AND THAT THE PERSON MAY CHOOSE TO CONSENT TO THIS BY TICKING OR NOT THE BOX PROVIDED FOR THIS PURPOSE IN THE INFORMED CONSENT FORM

- WHERE APPROPRIATE, THAT THE STUDY IMPLIES THE POSSIBILITY OF INCIDENTAL FINDINGS POTENTIALLY RELEVANT FOR THEIR HEALTH, AND THAT THE PERSON MAY CHOOSE TO BE INFORMED ABOUT THESE OR NOT BY TICKING THE BOXES PROVIDED FOR THIS PURPOSE IN THE INFORMED CONSENT FORM (SEE ALSO THE CNER’S TERMS OF REFERENCE FOR MANAGING INFORMED CONSENT AND PROCESS FOR COMMUNICATING THESE FINDINGS TO PARTICIPANTS). THE DIFFERENT TYPES OF POSSIBLE INCIDENTAL FINDINGS SHOULD BE DESCRIBED AS PRECISELY AS POSSIBLE, AND IT SHOULD BE SPECIFIED THAT ACCORDING TO THEIR NATURE, THEY MAY ALSO HAVE AN IMPACT ON THE DESCENDANTS WHERE APPROPRIATE

**Risks and possible inconveniences of the study**

- DESCRIBE THE RISKS OF POSSIBLE SIDE EFFECTS, INCONVENIENCES, ETC.

- SPECIFY IF APPLICABLE THAT AN INSURANCE IS FORESEEN TO COVER THE PERSON IN CASE OF DAMAGES RELATED TO THEIR PARTICIPATION IN THE STUDY

**Protection of private life**

DEPENDING ON THE PROJECT, PLEASE DESCRIBE PRECISELY:

- WHAT HAPPENS TO THE COLLECTED SAMPLES

- WHAT HAPPENS TO THE COLLECTED DATA

- WHO HAS ACCESS TO THE DATA (WHILE SPECIFYING THE FORM: IDENTIFYING, PSEUDONYMISED, ANONYMISED)

- HOW LONG THE DATA WILL BE STORED WITH JUSTIFICATION, TO LIMIT TO A MAXIMUM OF 15 YEARS AFTER THE END OF THE STUDY (WITH EXCEPTIONS), WHILE SPECIFYING IF THE DATA IS ANONYMISED OR DESTROYED AFTER THIS PERIOD

- HOW THE DATA WILL BE STORED

- THE PSEUDONYMISATION OF DATA IF APPLICABLE. IF DATA PSEUDONYMISATION IS FORESEEN, EXPLAIN WHAT THIS MEANS: “The data transmitted to the study sponsor or to other parties (PARTIES TO SPECIFY) will contain a reference code instead of your name. Your identity will thereby remain confidential. This is what we call “pseudonymised data”. The list linking the code to your name will be stored confidentially by the principal investigator. So only he/she will know your identity. This list will be stored during X years before being destroyed.”

- THE SECONDARY ANONYMISATION OR THE DESTRUCTION (AND AFTER HOW MUCH TIME THIS IS FORESEEN) IF APPLICABLE

- WHAT HAPPENS TO THE DATA IF THE PARTICIPANT DECIDES TO WITHDRAW FROM THE STUDY. IF APPLICABLE, EXPLAIN THAT THE PARTICIPANT CANNOT REMOVE THE DATA THAT HAS ALREADY BEEN ANALYSED BY THE MOMENT THEY DECIDE TO WITHDRAW BECAUSE THIS WOULD COMPROMISE THE STUDY / IS NOT POSSIBLE ANYMORE (DATA ALREADY ANONYMISED AND IDENTITY TRACING NO LONGER POSSIBLE F.EX)

- IN CASE OF TRANSFER OF PSEUDONYMISED SAMPLES / DATA OUTSIDE OF THE EUROPEAN UNION, SPECIFIY THAT THE APPLICABLE DATA PROTECTION LEGISLATION MAY BE LESS STRICT, AND, IF APPLICABLE, EXPLAIN TO THE PARTICIPANT THAT THEY NEED TO CONSENT EXPLICITLY TO THIS TRANSFER. ALSO EXPLAIN THAT AGREEMENTS BETWEEN THE DIFFERENT PARTNERS HAVE BEEN ESTABLISHED TO GUARANTUEE A DATA PROTECTION LEVEL THAT IS AT LEAST EQUIVALENT. THE TRANSFER OF DATA/SAMPLES IN ANONYMISED FORM IS TO BE FAVOURED.

- INDICATE THE COORDINATES OF THE DATA PROTECTION OFFICER (CAUTION: INDICATE COORDINATES IN LUXEMBOURG!)

- GUARANTEE MUST BE GIVEN TO THE PARTICIPANT THAT HIS DATA WILL BE PROTECTED IN ACCORDANCE WITH Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter: "General Data Protection Regulation"), respectively the law of 1 August 2018 on the organisation of the National Data Protection Commission and the general data protection regime (if the study is exclusively Luxembourgish) and more particularly articles 63 to 65 of this law.

- We also recommend that you also MENTION ALL THE RIGHTS OF THE DATA SUBJECTS, for example like this: *“You have the right to request from the controller access to, and rectification or erasure of personal data, or restriction of processing, or to object to processing, as well as the right to data portability according to the conditions foreseen in articles 15 to 21 of the General Data Protection Regulation. In addition, you have the right to lodge a complaint with the National Data Protection Commission (CNPD), if you think that the processing of your personal data violates the* *General Data Protection Regulation.”*

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**INFORMED CONSENT FORM**

TITLE OF STUDY

CONTACT PERSON FOR FURTHER INFORMATIONS / if applicable contact details of the DPO

With the support of NAME OF SPONSOR(S)

I hereby declare having received enough information about this study from the principal investigator, and having read the attached information sheet and having understood its meaning.

I am aware that my participation in this study is entirely voluntary and that I can withdraw at any time without condition.

My personal data will be treated in a strictly confidential way, as foreseen in the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 and the Act of 1 August 2018 on the organisation of the National Data Protection Commission and the general data protection framework (if the study is exclusively Luxembourgish) and more particularly the articles 63 to 65 of said Act. I understand the reasons for which these data are collected, treated and used in this study.

ACCORDING TO THE TYPE OF STUDY, THE PRINCIPAL INVESTIGATOR WILL ADAPT THE FORMULATION OF THE INFORMED CONSENT FORM BECAUSE CERTAIN TICK BOXES BELOW WILL BE APPLICABLE OR NOT.

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| I voluntarily agree to take part in this study according to the conditions described in the attached information sheet. | □ | □ |
| I agree to take part in the genetic part of the study. | □ | □ |
| I want to be informed about the scientific results of this research project. | □ | □ |
| I agree to the transfer of my pseudonymised samples / data outside the European Union, where the legislation on data protection could be less strict. | □ | □ |
| I agree to be recontacted by the person responsible for the study in the period during which my pseudonymised samples will be stored, for a potential participation in another research project. | □ | □ |
| In the event of an incidental finding (some of which, in particular germline mutations, could not only affect my future health, but also that of my children, brothers/sisters, parents...),  **I agree to receive such information through** my treating physician / the study responsible physician / a geneticist (CHOOSE APPLICABLE MENTION)**, to discuss the possible implications and to be referred to a local geneticist if needed.**  **[\_\_] yes [\_\_] no**  In making my decision, I confirm that I have been well informed and that I understand that the researcher has no obligation to actively search for such “findings”, which are incidental by definition, in my sample(s), and that in the case of the incidental finding of a germline mutation, this does not in any way constitute a diagnostic.  I have also been informed that if such a finding occurs, it will occur at the time of data analysis for this current project, or for future projects if I have consented to the secondary use of my samples/data in the separate informed consent form. This is also when I will be contacted again if I have ticked "yes" above. Finally, I confirm having been well informed that I can change my decision at any time.  → Consequences of my decision:  If I answer “no”, I will not receive any information about these incidental findings, nor will my relatives be informed.  If I answer “yes”, I will be informed of the incidental finding(s) through my treating physician / the study responsible physician / a geneticist. I will then be invited to discuss the possible implications and to be referred to a local geneticist if needed.  **If the answer to the question above is “yes”, and in case of an incidental finding that may be relevant for the health of a relative, and if I am not able to receive this information myself (including if I am deceased at the time this information is identified), I wish to designate a member of my family (representative) to whom these results could be communicated, who could discuss the implications with my treating physician or the study responsible physician, and be referred to a local geneticist if necessary.**  **[\_\_] yes [\_\_] no**  Name of my representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If I answer "yes", this means that I agree that my representative may receive such information, discuss the implications with my treating physician, and be referred to a local geneticist. | | |

Participant’s Name: Date:

Signature of Participant:

Part reserved for the principal investigator:

I hereby certify, NAME OF THE PRINCIPAL INVESTIGATOR, having informed the above participant about the objectives, the nature, the duration and the risks of this study and certify that he / she has agreed to take part in this study.

Date: Signature:

**Done in two copies, one to be kept by the participant and one by the principal investigator.**