EXPECTED ELEMENTS IN THE INFORMATION SHEET FOR SECONDARY USES - CNER template version from 15.05.2024

Date and Version number

**PARTICIPANT INFORMATION SHEET FOR SECONDARY USES OF SAMPLES AND/OR DATA COLLECTED IN THE STUDY "PRIMARY STUDY TITLE"**

**Basic introduction content:**

* describe the primary use foreseen by the primary study and explain what a secondary use is, i.e. a re-use of samples and/or data, for another research project, in this case limited to the same research area as the primary study;
* remind that consent to secondary uses of one's samples and/or data for other studies is voluntary, and that refusal of such secondary uses does not lead to exclusion from the primary study;
* specify how long the samples and data will be stored and may be subject to secondary uses if the person has consented;
* explain that withdrawal of consent for secondary uses is only possible for samples and data that have not yet been re-used, while also explaining why (e.g. because it would compromise the study, or is no longer possible if the data have already been anonymised/aggregated);
* remind that if they consent to secondary analyses of their samples, incidental findings are possible and that their expressed choice about sharing these with them or their relatives in the primary ICF will be respected. If the primary study ICF did not address this issue because there was no possibility of incidental findings in the primary study, a checkbox for this purpose should be added in this ICF dedicated to secondary uses (see checkbox for proposal No 4. in the tables that follow);
* specify that secondary uses may involve public or commercial/private partners but never include the sale of samples or data;
* specify where the participant can be informed of the secondary use projects (e.g. primary study website, ...);
* explain that the consent options presented in the document differentiate secondary uses according to:
  + whether the investigator remains the same or not,
  + whether data or samples are involved,
  + whether or not the planned analyses of the samples include genetic analyses.
* remind what is meant by pseudonymisation and anonymisation, as should normally have been done in the primary study information sheet;
* explain that in case of transfer of pseudonymised samples / data outside the European Union, the applicable data protection legislation may be less strict, and, if applicable, explain to the participant that they must give their explicit consent for this transfer. Also explain that agreements between the different partners will however be put in place to ensure a data protection level that is at least equivalent. Note: the transfer of data/samples in an anonymised form is to be encouraged;
* certify to the participant that their 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 Commission for Data Protection and the general data protection regime (if the project is exclusively Luxembourgish) and more particularly articles 63 to 65 of this law;
* mention the contact details of the DPO of the primary study;
* We also suggest that you mention all the rights of the persons concerned with regard to the protection of personal data, for example in this way:

"You have the right to request from the controller access to, rectification or erasure of personal data, or a restriction of processing; you have the right to object to processing and the right to data portability under the conditions set out in Articles 15 to 21 of the General Data Protection Regulation. If you consider that the processing of your data constitutes a breach of the General Data Protection Regulation, you may lodge a complaint with the National Commission for Data Protection (CNPD)."

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**INFORMED CONSENT FORM FOR SECONDARY USES OF SAMPLES AND/OR DATA COLLECTED IN THE STUDY "PRIMARY STUDY TITLE"**

**In the ICF for secondary uses, the following two tables with the different consent options must be included:**

**SECONDARY USES OF SAMPLES AND/OR DATA BY THE SAME INVESTIGATOR / RESEARCH TEAM / INSTITUTION:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| For other subsequent projects in the same field of research (to be clearly named here and which must be seizable for the individual) that are conducted **by THE SAME INVESTIGATOR / RESEARCH TEAM / INSTITUTION**: | | | | | |
| 1. I agree to the re-use of my pseudonymised or anonymised **data** | **No** | □ |  | | |
| **Yes** | □ |
| 1. I agree to the re-use of my pseudonymised or anonymised **samples** | **No** | □ |  | | |
| **Yes** | □ | * I also agree to **genetic analysis** being carried out on my pseudonymised or anonymised **samples** | **No** | □ |
|  | | | **Yes** | □ |
| 1. my choices expressed above remain valid if the proposed secondary use project involves a transfer outside the European Union of my samples and/or data | **No** | □ |  | | |
| **Yes** | □ |
| 1. Please note that this proposal only applies if I have agreed to the re-use of my **samples**:   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 (CHOOSE APPLICABLE MENTION). 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. | | | | | |

**SECONDARY USES OF SAMPLES AND/OR DATA BY OTHER RESEARCHERS:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| For other subsequent projects in the same field of research (to be clearly named here and which must be seizable for the individual) that are conducted **by other researchers**: | | | | | |
| 1. I agree to the re-use of my pseudonymised or anonymised **data** | **No** | □ |  | | |
| **Yes** | □ |
| 1. I agree to the re-use of my pseudonymised or anonymised **samples** | **No** | □ |  | | |
| **Yes** | □ | * I also agree to **genetic analysis** being carried out on my pseudonymised or anonymised **samples** | **No** | □ |
|  | | | **Yes** | □ |
| 1. my choices expressed above remain valid if the proposed secondary use project involves a transfer outside the European Union of my samples and/or data | **No** | □ |  | | |
| **Yes** | □ |
| 1. Please note that this proposal only applies if I have agreed to the re-use of my **samples**:   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 (CHOOSE APPLICABLE MENTION). 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 to the principal investigator of the primary study:

I, the undersigned, NAME OF THE PRINCIPAL INVESTIGATOR, hereby confirm that I have informed the above participant in accordance with the contents of the preceding secondary use information sheet, and that he/she has agreed to the re-use of his/her samples and/or data according to the choices expressed in this form.

Date: Signature:

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