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| HBM4EU TASK 7.5 TEMPLATE |
| CERTIFICATE OF INFORMED CONSENT |
| FOR PEOPLE LEGALLY ABLE TO PROVIDE CONSENT |

***INSTRUCTIONS ON HOW TO USE THIS TEMPLATE***

*This is a template, which can be used to develop a tailored certificate of informed consent for participants in HBM4EU surveys, who are legally eligible to provide their informed consent. According to GDPR1, this applies to ages over 16.*

*To use this template, change the red text with appropriate wording and delete all instructions and brackets in italicized blue text. You may introduce further changes, as required by the study design and national requirements, while ensuring compliance with GDPR.*

On 31.01.2020, this template was updated to include the contact details of the Data Protection Officer (DPO) of the legal entity carrying out the study, as required by the European Commission’s General Data Protection Regulation (GDPR, section 2, Art. 13 and 14). All changes compared to the previous version, are highlighted in grey.

*\_\_\_\_\_\_\_\_*

*1GDPR is regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1‑88.*

***Encoding of task 7.5 templates***

*The templates prepared by task 7.5 are given an acronym, shown in the footer, which denotes the type, version, year of last revision and follows the key:*

*TYPE: CIC = Certificate of Informed Consent*

*TARGER AUDIENCE: AD = Adults*

*VERSION: Vxx = Version No.*

*DATE OF LAST REVISION: DD-MM-YY*

**CERTIFICATE OF INFORMED CONSENT**

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| **Study description** | |
| Title |  |

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| --- | --- | --- | --- |
| **Researcher identifier** | | | |
| Name |  | [Telephone](Tel:xxxxxx) |  |
| Department |  | Email |  |
| Institution |  | | |
| Address |  | | |

**Participant Statement of Informed Consent**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| I, the undersigned, hereby confirm the following: | | | | | Initials |
| 1. | I was given the “Information for Participants” leaflet, which explains the following related to the research study:   * the purpose of the study and how it will be carried out * what my participation involves * my rights (to withdraw, to be forgotten and remove any data/samples provided, to choose whether I wish to be informed of my personal results) * my commitments. | | | |  |
| 2. | I had the opportunity and time (at least 24 hours) to consider and comprehend the information in the “Information for Participants” leaflet. | | | |  |
| 3. | I had the opportunity to ask questions and I received satisfactory answers. | | | |  |
| 4. | I understand that my participation in the research, as defined in the “Information for Participants” leaflet, is voluntary and that I am free to withdraw at any time (without giving any reason and without my medical care or legal rights being affected), by following the procedure explained in the “Information for Participants” leaflet. | | | |  |
| 5. | I understand that if I choose to withdraw from the study, data related to me and collected prior to my withdrawal will continue to be used solely for the purpose of allowing the research to be completed. These data will be “coded” (my name will be replaced by a code) to protect my identity. | | | |  |
| 6. | I consent that the *[* *Specify* name of organization, represented by …………. *(specify the* name and function of the data/sample controller*) ]* will have the exclusive access to my identifying personal information and will encode my data and samples according to the currently available safeguards, in such a way that other users of my data cannot trace back to me. I understand that the Data Protection Officer of the *[specify* (name of the legal entity)*]* is at my disposal for questions or concerns related to data protection and may be reached at the following contact information: *[specify* (name and contact information of the Data Protection Officer of the legal entity)*]*. | | | |  |
| 7. | I consent to *[Specify:* the long-term *OR* *specify* duration*]* storage and use of my coded samples *[specify* (type)*]* and coded personal data collected in this study for research related to *public health* and *environmental health* purposes, even in the event of my death or my becoming incapacitated. | | | |  |
| 8. | I consent that my coded samples and/or data can be transferred to specialized laboratories, biobanks, databases, data infrastructures, research establishments, administrative authorities and institutions in the European Union and associated countries or used for public announcements and reports within the scope of the research. | | | |  |
| 9. | I consent that the *[* *Specify* name of organization, represented by …………. *(specify the* name and full contact details *of* responsible person *]* may contact me in the future for public and environment health-related research purposes and/or to inform me about my personal results, if I choose to receive them. | | | |  |
| 10. | I understand that I have the right to receive my personal results as stated in the “Information for Participants” leaflet and I indicate my preference as follows *(please mark* ***one*** *option only)*:  □ I wish to **receive** my personal results  □ I wish to **receive** my personal results **only if** they exceed the health-based guidance values used in the study (wherever applicable)  □ I do not wish **to receive** my personal results. | | | |  |
| 11. | I understand that I will not benefit financially from taking part in this study. | | | |  |
| My signature below indicates my consent to take part in the study. | | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_ | |
| Name of Participant | | Signature of Participant | Location | Date | |

If the participant consents to participate in the study but is not able to provide signature, the following must be completed:

|  |  |  |  |
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| I witnessed the accurate reading of the “Information for Participants” leaflet and the “Certificate of Informed Consent” to the participant.  I witnessed that the participant had time (at least 24 hours) to consider the information and the opportunity to ask questions.  I confirm that the participant was not coerced into giving consent, and that his/her consent was given freely and voluntarily and without any objection raised. | | | |
| Thumb print of the participant | | |  | | --- | |  | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_ |
| Name of witness | Signature of witness | Location | Date |

**Statement by the researcher / person taking consent**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| I made sure, to the best of my ability, that the participant understands that the following will be done:  *[describe the specifics of the study, which relate to the participant:*  1. <<……………….>>  2. <<……………….>>  3. <<…………………>>  4. <<………………..>> *]*  I confirm that the participant was given time (at least 24 hours) to consider the information, had the opportunity to ask questions about the study and that all the questions asked have been answered truthfully and to the best of my ability.  I confirm that the participant was not coerced into giving consent, and that his/her consent was given freely and voluntarily and without any objection raised.  **A copy of this Certificate of Informed Consent was provided to the participant.**   |  |  |  |  | | --- | --- | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_ | | Name of researcher /  person taking the consent | Signature of researcher /  person taking the consent | Location | Date | |

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| For internal use only: | Participant Code: |  |