Information Sheet EUR Informed Consent Form

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This information sheet provides context for creating the Informed Consent Form for your research.
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INFORMATION SHEET – Instructions

This information sheet provides practical and relevant context for creating the Informed Consent Form for your research. At the bottom of this information sheet you will find the exact requirements, as stated in the General Data Protection Regulation (http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf) with regards to Informed Consent.

Introduction
Briefly state who you are and that you are inviting the research participant or data subject to participate in your research. Inform the data subject that he or she is free to talk to anyone they feel comfortable talking with, about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask additional questions at any time.

Purpose of the research
Explain the research question and purpose of the research in layman's terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have.

Type of research intervention
Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves an interview, a questionnaire, or a series of finger pricks or administering a vaccine.

Participation selection
Indicate why you have chosen the data subject to participate in your research. People might wonder why they have been chosen and may be fearful, confused or concerned.

Voluntary Participation
Indicate clearly that the data subject can choose to participate or not. Think of scenario's for your data subject when he or she is placed in a situation where in a practical sense, the data subject does not feel free to opt out, due to peer pressure or otherwise.

Procedures
Provide a brief introduction to the format of the research study. Explain the type of questions that the data subjects are likely to be asked in the focus group, the interviews or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment,

inform the participant of this, and indicate which addition steps you have taken for the data subject to trust the research design and you.

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Risks
Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

Benefits
Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

Reimbursements
State clearly what you will provide the participants with as a result of their participation.

Confidentiality
Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality.

Sharing the Results
Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Note that the data provided by the participant, up to the moment of withdrawal (of consent), can be used in the research. This should be made clear to the participant. From the moment the consent is withdrawn, no new data may be gathered or processed from this participant. The Tailor this section to ensure that it fits the group for whom you are seeking consent. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted.

How Informed Consent is described in the General Data Protection Regulation
(http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf)

Article 4. Definitions
(11) 'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;

Article 6. Lawfulness of processing
1. Processing shall be lawful only if and to the extent that at least one of the following applies:
(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

Article 7. Conditions for consent
1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.
2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.
3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.
4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

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Recitals

(32) Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another
statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject's consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

(**33)** It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

(**65)** A data subject should have the right to have personal data concerning him or her rectified and a 'right to be forgotten' where the retention of such data infringes this Regulation or Union or Member State law to which the controller is subject. In particular, a data subject should have the right to have his or her personal data erased and no longer processed where the personal data are no longer necessary in relation to the purposes for which they are collected or otherwise processed, where a data subject has withdrawn his or her consent or objects to the processing of personal data concerning him or her, or where the processing of his or her personal data does not otherwise comply with this Regulation. That right is relevant in particular where the data subject has given his or her consent as a child and is not fully aware of the risks involved by the processing, and later wants to remove such personal data, especially on the internet. The data subject should be able to exercise that right notwithstanding the fact that he or she is no longer a child. However, the further retention of the personal data should be lawful where it is necessary, for exercising the right of freedom of expression and information, for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the
exercise of official authority vested in the controller, on the grounds of public interest in the area of public health, for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, or for the establishment, exercise or defence of legal claims.