INFORMATION FOR RESEARCHERS CONCERNING INFORMED DECISION MAKING: WHAT IS AN INFORMED CONSENT FORM?

To assist researchers, WHO has developed Informed Consent Form templates for various types of research studies. Click here to view these.

Whenever you are proposing research with human participants you must provide a form, known as an Informed Consent Form (ICF), with each proposal to indicate that the research participant has decided to take part in the research of her/his own free will. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, you must provide a separate informed consent form for each group which has been tailored specifically for them. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form.

Once approved by the WHO ethics review committee (ERC), the consent forms become part of the project protocol. Forms should be written in the prospective participants' mother tongue, and when this is not English, an English language translation should be provided as well. If you prefer, consent forms can be written in the language which the researcher is most comfortable with and translated into the participants' mother tongue and English. Ideally, translated consent forms should be back-translated and compared with the original to ensure accuracy. For review purposes, both the local language and the English version of the ICF should be submitted.

For multi-centre research studies, a common consent form will be taken as a minimum requirement to which additions may be made as dictated by local circumstances. In such cases, the common consent form should be written in either the researcher's mother tongue, or the language which the researcher is most comfortable with, and translated into English and other languages as required. Institutes participating in multi-centre trials must inform WHO whether they will use the common consent form and, if the common consent form will not be used, the institutes should provide a copy of the amended and/or translated version that will be used.

The consent form has two parts: (*a*) an **information sheet** describing the research and the nature of the participant's involvement in it, and (*b*) a **certificate of consent** attesting to the participant's consent. Both parts should be written in sufficiently large letters and in simple language so that the participant can easily read and understand the contents. The information sheet should be written in third person (e.g. "you will meet with the researcher…") whereas the certificate of consent should be written in first person (e.g. "I have been informed that….). Medical terminology should be avoided in writing up the informed consent form.

The information sheet is given or read to each prospective participant. Any questions the participant may have are then answered and, if consent is given, the certificate is signed by the participant. If consent is oral, the certificate is signed by a literate witness who was present when the information was read to the participant and who confirms that the information was understood, and consent was given freely. The researcher/staff member who provided the information to the participant also signs the certificate, likewise confirming that the information was provided and understood, and that consent was voluntary. A signed certificate of consent must be obtained in this way for each participant admitted to the research study and a copy of the entire informed consent form must be offered to the participant.

There are often times when the agreement of community leaders or representatives is either mandatory or good practice. When community agreement is advised, it is obtained prior to, but does not replace, the consent of individual participants. In general, community agreement is obtained through a process of discussions and meetings with community leaders and does not require signed agreement. However, there are some countries

and communities which require written evidence of community agreement. It is the researcher's responsibility to become aware of, and respect, these requirements.

When research involves children or people considered to be unable or not competent to sign for themselves, a consent from a parent or guardian is required. *However, children or others considered to be unable to sign for themselves, should be given the opportunity, where at all appropriate, to have their permission or concerns recorded as well.* This is known as Assent and there is a separate form for the recording of assent. The age at which assent is required depends upon local legal requirements or, in their absence, upon both the local culture and the content of the research. In general, researchers should consider obtaining assent from children over 7 years with mandatory assent required from the age of 12. Assent which is denied must be taken very seriously.

If the research involves HIV testing, testing for Hepatitis B or C, pregnancy testing, or other tests that may have further implications for follow up or treatment, participants must be offered pre and post-test counselling relevant to the tests. If any of these tests are pre-requisites to the primary research, or are required at any time during the course of the main research, an additional and separate informed consent for permission to test will be necessary.

In writing up the **information sheet** take note of the following points:

- Indicate that this is a **research study** to distinguish it from routine care.

- Clearly state that participation is **voluntary** and, if applicable, that current care will not be negatively affected. Stating the voluntary nature of participation at the outset allows the potential participant to hear the rest of the information in that context and to hear it when they are most alert. It can be repeated near the end of the information sheet as well.

- **Explain why** the research is being done and why the prospective participant is being asked to participate.

- Describe, in sequence, **what will happen** in the course of the research, giving enough detail for the participant to gain a clear idea of what to expect.

- Explain the nature, likelihood and treatment of **anticipated risks, discomfort or adverse effects**, including psychological and social risks, if any. Where relevant, include a comparison with risks posed by standard treatments or drugs, and an indication of whether the drug or procedure under investigation bears risks equal to, greater than, or less than the standard. If the risks are unknown or a comparative risk cannot be given it should be so stated.

- Explain whether or not the research procedures offer any **benefits** to the participant or to others. The research may not offer any benefit to the participant and this should be stated clearly.

- Where relevant, explain what will be done with the **'excess' biological samples** that may be taken as part of the research protocol - how soon after the research will they be discarded or destroyed or for how long will they be stored, how will they be stored and who will have access to these samples and under what circumstances. Who will have the responsibility to eventually destroy or discard these samples? Note that if unused samples are to be stored for future use, further consent is needed from the participant and perhaps from the community in cases where the research is of a nature that the community may be involved or affected. *This is discussed in the last paragraph of this document.*

- State that all records are to be kept **confidential**. If absolute confidentiality cannot be guaranteed, explain why this is so. Explain the extent to which the confidentiality of participant-specific information will be protected during the research and in any resulting public disclosures at meetings or in publications. Also state which persons other than the researchers may have access to the records and/or to whom information

may be disclosed. State where and in what form participant-specific information will be stored, and when, how and by whom it will be destroyed.

- State that the participant has the **right to refuse to participate or withdraw** from the research at any time without their current or future care being affected. State what alternative treatments or procedures are available for both those who choose not to participate in the research and for those who withdraw.

- Explain how you will be **sharing the research findings with participants**. If you have a plan and a timeline, state this in the information sheet. You should also state that you will be sharing the research findings more broadly and provide information about how this is to be done, i.e. through scientific reports.

- ***Contact information*.** The name, address and telephone number must be included on the form of the person(s) to be contacted by the research participant if they have questions about, or experience any problems during the course of, the research. These should be persons who are available on site, intimately involved with the research project and easily accessible to research participants, not chairpersons of ethics committees or deans of schools or heads of departments.

- The **Certificate of Consent** is the second part of the Informed Consent Form and is not a stand alone document. By presenting it as a continuation, or part two, of the informed consent rather than as its own separate document, both researchers and participants can be assured that the information about the study and about the participant's rights have been shared with the participant.

The certificate of consent should be written the first person (e.g. "I have been informed…") and should have a paragraph such as the following:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study .

The informed consent document is to be signed and dated by the participant or, when the participant is illiterate or physically unable, by a literate witness who ascertains that it was understood and confirms that consent was given freely. Whenever possible, the witness should be selected by the participant and he/she should not be connected with the research team. Whenever feasible, the recruitment of illiterate participants should take place in the presence of a literate witness.

The witness and the researcher each sign under a statement such as the following:

I have accurately read or witnessed the reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that consent was given freely.

- *Statement of Consent for Storage and Future Use of Unused Samples*. If the protocol calls for the storage and future use of samples, broad informed consent should be obtained. This separate consent form should provide the reasons for requesting storage of the samples (or data), details about their storage (where, how, for how long, and final disposition) and possible future uses, that participants have the right to decide about such future use, to refuse storage, and to have the material destroyed; the purpose of the biobank were samples will be stored, the conditions and duration of storage (e.g., if samples will either be destroyed after a certain period of time or kept indefinitely); the ways in which the donor can contact the biobank custodian; the safeguards that will be taken to protect confidentiality as well as their limitations. It is important that this statement of consent be presented in clear language and that the concepts can be readily understood.

For more information click to view CIOMS Guidelines, Guideline 11.