Globethics Repository



The Process of Obtaining Informed Consent

This page was generated automatically upon download from the Globethics Repository. More information on Globethics see https://www.globethics.net. Data and content policy of Globethics Repository see https://repository.globethics.net/pages/policy.

Item Type	Postprint
Authors	World Health Organization (WHO)
Publisher	World Health Organization (WHO)
Rights	With permission of the license/copyright holder
Download date	2026-11-19 20:29:01
Link to Item	http://hdl.handle.net/20.500.12424/217843

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – HTTP://INTRANET.WHO.INT/HOMES/RPC/ERC – HTTP://WWW.WHO.INT/RPC/RESEARCH_ETHICS

The Process of Obtaining Informed Consent

1. Obtaining genuine informed consent from research participants is best thought of as a process of sharing information and addressing questions and concerns, rather than simply obtaining a signature on a prescribed form.

2. It starts with the researcher developing an awareness of national or regional guidelines, and may involve discussions with, and the involvement of, the community and/or discussions with the family members of potential participants. Participants must then give their individual consent to participate on an informed consent form (ICF) developed specifically for the research project.

3. There are very few research situations which do not require the participant's signature on an informed consent form. Permission from an ethics review committee is always necessary for waiving off this requirement.

4. Researchers should follow an appropriate and culturally-sensitive process of information sharing leading up to, and including, obtaining the participant's signature on the informed consent form.

5. This process may continue even after the signature is obtained as it is often appropriate for researchers to check back with participants throughout the research to ensure continued consent or because a new consent is required for an additional or changed intervention.

6. This document provides information which may be helpful to researchers as they consider the informed consent process for their research.

I. Awareness of, and consultation with, national and/or regional health research bodies

- Be aware of existing national and/or regional health research guidelines which may set out specific expectations to protect the interests and well-being of participants, their communities and the national health research system

- Consult national and/or regional research institutions on any proposed human subject research which will take place within their boundaries

- Where appropriate, consult with the local leadership or, when the research involves vulnerable populations, with the organizations representing or working in the interests of potential participants.

- At all stages of the informed consent process, be prepared to discuss the capacity-building potential of the research and the benefits for the community/country/region, as well as any benefits for individual participants.

Researchers should note that prior to submitting proposals to the ERC for review, the research proposal must have been submitted for review by a national/local IRB.

II. Discussions with community leadership

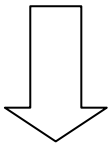
- Obtaining the agreement of local community leadership for the proposed research is almost always good research practice and is mandatory in some communities.
- Agreement from the community leadership is obtained prior to, but *does not replace*, the consent and/or assent of individual participants.
- Community consent is generally obtained through a process of dialogue with the community leadership and often does not require written agreement.
- There are, however, some countries and communities which require written evidence of consent and of the nature of any collaboration between the community and the proposed research. It is the researchers' responsibility to become aware of, and respect, these requirements.
- While support from the community leadership can lead to research practices which are collaborative, culturally-sensitive and which facilitate a more supportive research environment, researchers should be aware that what constitutes community leadership is not always clear, nor always ethically supportable, and that consultation does not necessarily result in agreement.

III. Recruiting and informing research participants

- Researchers may meet individually or in small groups with potential participants in order to recruit and inform them of the research.
- Sometimes, however, broader and more open approaches, such as information posters, brochures, announcements and community meetings may be better ways of introducing community members to the research which they are being invited to participate in.
- In all situations, the information that is shared with the community and potential participants must be provided in a manner that is understandable to participants and which, therefore, allows them to make an informed decision.

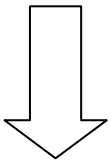
IV. Knowing and respecting community practices

- The degree of autonomy that individuals have to make decisions about their lives, including whether or not to agree to be a participant in a research study, varies among cultures.
- In some cultures, it is the norm for the head of a household to either make all such decisions or to lead the group towards a decision. A husband, father or brother may traditionally have the responsibility for decisions involving a wife, mother or a daughter of any age.
- In seeking informed consent, the researcher must consider these norms and traditions while still seeking the individual informed consent of the potential research participant.
- The research participant must give her or his own consent to participate even when consultations with other family or community members has occurred.
- In all situations, researchers should be prepared to recognize unspoken reluctance on the part of potential participants and to respect their wishes.



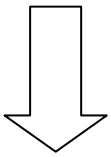
V. Accepting oral consent

- Oral consent is acceptable from research participants who are illiterate and, therefore, cannot read or sign informed consent forms.
- However, the informed consent process requires that researchers ensure firstly, that the information they provide about the research is in an understandable form and, secondly, that a literate witness is available to sign on behalf of the participant after the participant has given oral consent.
- Oral consent may also be audio-recorded and this recording witnessed as further confirmation.
- In additon to the signiture of a literate witness, agreement of participants who are illiterate should be indicated by including his/her thumb print on the ICF.
- Researchers should do their best to ensure that witnesses are not part of the research team. Whenever possible, participants should choose their own witness.
- There are very few situations other than illiteracy in which oral consent is acceptable and these *always* necessitate prior approval from an IRB and/or the ERC. It is, for example, possible that written consent may be waived if there is a possibility of unsupportable danger to the participant as a result of signing or when there is minimal risk coupled with anonymity. However, the vast majority of research requires written consent either of the participant or, in the case of illiteracy, of a literate witness.



VI. Obtaining consent and assent in research involving children

- Before seeking consent and assent to involve children in research, it must be demonstrated that comparable research cannot be done with adults to the same effect and scientific impact.
- Once it has been determined that the research should be permissible, researchers must obtain parental/guardian consent on an ICF for all children.
- WHO supported research follows the Convention on the Rights of the Child where child means 'every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier.'
- Children sufficiently able to understand the proposed research should have the opportunity to be informed about the research, to have their questions and concerns addressed and to express their agreement or lack of agreement to participate.
- While the age at which this informed assent should be taken varies, researchers should consider asking for assent from children over the age of seven years with assent taken from all children over the age of twelve years.
- Children express their agreement to participate on an informed assent form (IAF) written in age appropriate language. This form is **in addition to**, and *does not replace*, parental consent on an ICF.
- Assent which is denied by a child should be taken very seriously.



VII. Obtaining consent from vulnerable populations

- When seeking consent from participants in vulnerable populations, researchers should ensure that the participants will not be exploited, including being placed in situations which compromise their safety or dignity and which place them in a position of even greater powerlessness.
- Researchers may need to make extra allowance to ensure that the consent is genuine and does not place added risk or stress on the participant.
- As with all WHO supported research, participants may be reimbursed for expenses incurred as a result of the research and compensated for time lost from work. WHO does not support inducements to participate.

The type of information which should be provided to potential participants can be found in the document titled

Information for Researchers Concerning Informed Decision-making: What is an Informed Consent Form.
Templates for informed consent and assent forms are also provided together with examples. *Click here to view these*.

Guidance documents and international guidelines concerning ethics and informed consent can be found by *clicking here*.