

## Marie Stopes International

# Informed Consent Guidelines for Research

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## Introduction

*'[Informed consent is] given by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation'*

Council for International Organizations of Medical Sciences (CIOMS)

MSI's organizational strategy, ***The Power of 10*** places MSI's clients - underserved women and couples – at the centre of its efforts. As MSI strives to deliver high quality services to millions through its innovative health service delivery models, it also emphasises the importance of providing informed choice for their clients. In order to ensure the effectiveness of these interventions, MSI collects and analyses personal data from their clients, prospective clients, and service providers through various research, monitoring, and evaluation (RME) activities. This information can include personal identifiable data or a client's family planning/safe abortion behaviours that can increase the client's vulnerability within her community. Therefore, the informed consent process becomes critical to ensure that MSI respects clients and other research participants, and protects the information collected from them.

Informed consent is one of the primary ethical considerations in research involving human subjects, and embodies the three fundamental principles of research ethics:

- 1) respect for persons,
- 2) beneficence (i.e. maximize possible benefits, and do no harm), and
- 3) justice.

Informed consent is not just a legal requirement or a document to be signed, but rather an on-going communication process. It occurs between the research team and the participant to ensure that participants continue to understand what the research is about and what their participation involves. It requires the participation of numerous people, such as researchers, ethics committees and community representatives. Research team members are responsible for administering consent, ethics committees review the consent forms to ensure that they are appropriate and complete, and community members can assist the research team in designing culturally relevant informed consent forms.

It is an obligation for researchers across the MSI partnership to obtain appropriate informed consent from participants in MSI research studies before recruiting them into the study. For researchers carrying out RME activities across the MSI partnership, this document seeks to provide guidance on:

- 1) drafting an informed consent form (ICF); and
- 2) administering informed consent.

## 1. Drafting an Informed Consent Form (ICF)

- **Language to be used in the ICF**

The language used for written information about the study, including the ICF, should be non-technical, practical and understandable to the study participant (or the participant's legally acceptable representative, where applicable).

The ICF should not contain any language that causes the study participant to waive or to appear to waive any legal rights or release the Principal Investigator (PI), MSI, the donor and their agents for negligence.

The MSI ERC can only review English versions of the ICF. It is expected that the English version included in the protocol submission is an accurate translation of any ICF in any other language that will be used.

- **Information to be included in the ICF**

Both the informed consent discussion and the written ICF (and any other written information to be provided to participants) should include explanations of the following:

- a. That the study involves research.
- b. The purpose of the study.
- a. The study procedures to be followed, including all invasive procedures.
- b. The study participant's responsibilities.
- c. The reasonably foreseeable risks or inconveniences to the study participant.
- d. The reasonably expected benefits. (When there is no intended benefit to the participant, the participant should be made aware of this).
- e. The reimbursement or incentive, if any, provided to the participant for participating in the study.
- f. The anticipated expenses, if any, provided to the participant for his or her involvement in the study.
- g. The voluntary nature of the study participant's involvement in the study and the fact that the participant may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.
- h. The confidentiality of records containing personal identifiable data. (If the results of the study are published, the study participant's identity will remain anonymised).
- i. The fact that the study participant (or the study participant's legally acceptable representative) will be informed in a timely manner if information becomes available that may be relevant to the study participant's willingness to continue in the study.

- j. The person(s) to contact for further information regarding the study and the rights of study participants, and whom to contact in the event of a study-related injury or problem. (Relevant contact details of such persons should also be provided).
- k. Foreseeable circumstances and/or reasons for which the research team may terminate the study participant's involvement in the study.
- l. The expected duration of the study participant's involvement in the trial.
- m. The approximate number of study participants involved in the study.
- n. If tissues/bio-samples are taken from the study participant, a clause covering the use of study data for future research.

- **Ethics committee approval of ICF/written information**

The PI should have written approval for the protocol's ICF(s) from the ethics committees who review the study, as well as any other written information to be provided to study participants.

- **Revisions of ICF and need for ethics committee review**

The ICF (and any other written information to be provided to participants) should be revised whenever important/new information becomes available that may be relevant to participant's consent (e.g. new information on the side effects of a product or device). This revised ICF should be shared with the participant in a timely manner. Any revised ICF (and written information) must receive ethics committee review and approval in advance of being shared with the study participants.

## **2. Administering Informed Consent**

- **Screening potential participants before informed consent**

Research teams often need to screen participants to determine their eligibility before recruiting them into the study. We consider screening to be a short series of non-invasive questions, and will consider the screening tools on a case by case basis to determine whether they need their own consent form. When asking screening questions to potential study participants, it is important that they are asked in a private, safe setting.

- **Coercion and sufficient time for informed consent**

The PI and research team should not coerce or unduly influence participants to enrol or to continue in a research study.

Before informed consent may be obtained, the PI (or a person designated by the PI) should provide the study participant ample time and opportunity to inquire about the details of the study and to decide whether or not to participate, and discuss with family members if he or

she wishes. All questions about the study should be answered to the satisfaction of the study participant (or the study participant's legally acceptable representative).

- **Signing/marking the ICF**

The ICF, and any other written study information provided, should be read to the study participant and explained. Once the participant has orally consented, the ICF should be signed and personally dated both by the participant and by the person who administered informed consent.

The study participant should either sign or make their mark with a thumbprint (in cases where the study participant is illiterate). [Please see below for verbal consent.]

If the study participant is unable to either sign their name or provide his or her thumbprint, then the consent is considered declined and the person may not participate in the study. The research team must document the details of when a client cannot successfully complete the informed consent process and communicate these details to their Research Advisor on the MSI RME team.

- **Verbal consent**

In circumstances where obtaining a signature (or a thumbprint in the case of illiterate study participants) may create harm or put the participants at risk, the ERC will consider projects which propose a verbal consent process with the following conditions:

- That a clear explanation is provided in the research protocol as to why written IC is impossible or why obtaining a signature or thumbprint may create harm or risk.
- That evidence that the decision to conduct oral consent has been taken with local representatives (preferably from the communities/groups in which the research is being conducted).
- That the information sheet provided to study participants and the training for interviewers clearly state the IC procedures and the right of a participant to decline or to withdraw at any time without explanation.
- That the protocol state how verbal consent will be confirmed, e.g. the researcher administering informed consent will sign to confirm that all information about the study was provided and the participant verbally consented to taking part.
- That the research protocol clearly outline how the ethical implementation of verbal consent will be monitored, e.g. regular feedback from those administering the informed consent to supervisors.

All study protocols containing verbal-only consent will be subject to full review by the ERC.

- **Provision of a copy of the signed ICF/other written study information**

Prior to participation in the study, the participant (or the participant's legally acceptable representative) should be offered a copy of the signed and dated written informed consent form and any other written information provided to the participants. The study participant may choose to decline their copy, but the research team should offer a copy. In cases where it would be considered harmful or not possible to provide study information in writing, reasons should be justified in the protocol.

For the duration of the study, the participant should receive a copy of the signed and dated ICF updates and a copy of any amendments to any written information provided to participants.

## Appendix A – Further Resources on Research Ethics and Informed Consent

Council for International Organizations of Medical Sciences. *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS; 2002.

([http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf))

International Conference on Harmonisation, Guideline for Good Clinical Practice.

(<http://ichgcp.net/pdf/ich-gcp-en.pdf>)

Nuffield Council on Bioethics. *The ethics of research related to healthcare in developing countries*.

London: Nuffield Council on Bioethics; 2002.

(<http://www.nuffieldbioethics.org/research-developing-countries>)

World Medical Association. *Declaration of Helsinki*, last revised 2000.

(<http://www.wma.net/e/policy/bc.htm>)