INFORMED CONSENT PROCESS

5.0 The researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants. This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research. Informed consent is a continuous process involving three main components – providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual's freedom of choice and respects the individual's autonomy.

5.1 Requisites

5.1.1 The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent.

5.1.2 The consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements.

5.1.3 In the case of an individual who is not capable of giving voluntary informed consent, the consent of LAR must be obtained. See section 6 for further details.

5.1.4 It is mandatory for a researcher to administer consent before initiating any study related procedures involving the participant.

5.1.5 It is necessary to maintain privacy and confidentiality of participants at all stages.

5.2 Essential information for prospective research participants

5.2.1 Before requesting an individual's consent to participate in research, the researcher must provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant.

5.2.2 The ICD has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF). Information on known facts about the research, which has relevance

Box 5.1 Essential and additional elements of an informed consent document

An informed consent form must include the following:

1. Statement mentioning that it is research
2. Purpose and methods of the research in simple language
3. Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods
4. Benefits to the participant, community or others that might reasonably be expected as an outcome of research
5. Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study
6. Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality
7. Payment/reimbursement for participation and incidental expenses depending on the type of study
8. Free treatment and/or compensation of participants for research-related injury and/or harm
9. Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled
10. The identity of the research team and contact persons with addresses and phone numbers (for example, PI/Co PI for queries related to the research and Chairperson/Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)

In addition, the following elements may also be required, depending on the type of study:

1. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected
2. If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pre-test- and post-test counselling
3. Insurance coverage if any, for research-related or other adverse events
4. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research. Other specifics are as follows:
   - i period of storage of the sample/data and probability of the material being used for secondary purposes.
   - ii whether material is to be shared with others, this should be clearly mentioned.
   - iii right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research.
   - iv risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.
   - v post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.
   - vi Publication plan, if any, including photographs and pedigree charts.

   See section 11 for further details.

to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.

5.2.3 Adequate time should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research.

5.2.4 Essential elements of an informed consent document are given in Box 5.1.

5.3 Responsibility of researchers

5.3.1 The researcher should only use the EC approved version of the consent form, including its local translations.

5.3.2 Adequate information necessary for informed consent should be communicated in a language and manner easily understood by prospective participants.

5.3.3 In case of differently abled participants, such as individuals with physical, neurological or mental disabilities, appropriate methods should be used to enhance the participants' understanding, for example, braille for the visually impaired.

5.3.4 There should be no restriction on the participant's right to ask questions related to the study or to discuss with family and friends or take time before coming to a decision.

5.3.5 The researcher should not give any unjustifiable assurances or influence or intimidate a prospective participant to enroll in the study.

5.3.6 The researcher must ensure that the participant is competent and has understood all aspects of the study and that the consent is given voluntarily. Where the participant and/or the LAR are illiterate, an impartial literate person, not connected to the research, should be present throughout the consent process as witness.

5.3.7 The researcher should administer a test of understanding whenever possible for sensitive studies. If need be, the test may be repeated until the participant has really understood the contents.

5.3.8 When a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely.

5.3.9 Reconsent or fresh informed consent of each participant must be taken under circumstances described in section 5.8.

5.3.10 The researcher must assure prospective participants that their decision whether or not to participate in the research will not affect their rights, the patient–clinician relationship or any other benefits to which they are entitled.

5.3.11 Reimbursement may be given for travel and incidental expenses/participation in research after approval by the EC.

5.3.12 The researcher should ensure free treatment for research related injury (disability, chronic life-threatening disease and congenital anomaly or birth defect) and if required, payment of compensation over and above medical management by the investigator and/institution and sponsor(s), as the case may be.

5.3.13 The researcher should ensure that the participant can continue to access routine care even in the event of withdrawal of the participant.

5.4 Documentation of informed consent process

Documentation of the informed consent process is an essential part of this exercise.

5.4.1 Each prospective participant should sign the informed consent form after going through the informed consent process of receiving information, understanding it and voluntarily agreeing to participate in the research.

5.4.2 In case the participant is incompetent (medically or legally) to give consent, the LAR's consent must be documented.

5.4.3 The process of consent for an illiterate participant/LAR should be witnessed by an impartial literate witness who is not a relative of the participant and is in no way connected to the conduct of research, such as other patients in the ward who are not in the study, staff from the social service department and counsellors. The witness should be a literate person who can read the participant information sheet and consent form and understand the language of the participant.

5.4.4 If the participant cannot sign then a thumb impression must be obtained.

5.4.5 The researcher who administers the consent must also sign and date the consent form.

5.4.6 In the case of institutionalized individuals, in addition to individual/LAR consent, permission for conducting the research should be obtained from the head of that institution.

5.4.7 In some types of research, the partner/spouse may be required to give additional consent.

5.4.8 In genetic research, other member of a family may become involved as secondary

participants if their details are recorded as a part of the family history. If information about the secondary participants is identifiable then their informed consent will also be required.

5.4.9 Online consent may be obtained, for example, in research involving sensitive data such as unsafe sex, high risk behaviour, use of contraceptives (condoms, oral pills), or emergency contraceptive pills among unmarried females in India etc. Investigators must ensure that privacy of the participant and confidentiality of related data is maintained.

5.5 Electronic consent

Electronic media can be used to provide information as in the written informed consent document, which can be administered and documented using electronic informed consent systems. These are electronic processes that use various, and possibly multiple, electronic formats such as text, graphics, audio, video, podcasts or interactive websites to explain information related to a study and to document informed assent/consent from a participant or LAR.

5.5.1 The process, electronic materials, method of documentation (including electronic/digital signatures), methods used to maintain privacy of participants, confidentiality, and security of the information as well as data use policies at the research site must be reviewed and approved by the EC a priori.

5.5.2 The electronic consent must contain all elements of informed consent in a language understandable by the participant. See Box 5.1 for further details.

5.5.3 The PI or her/his designee must supervise the process.

5.5.4 In addition to electronic consent, if required a paper/soft copy of the document is needed for archiving and a paper/soft copy is also given to the participant.

5.5.5 Interactive formats, if used, should be simple to navigate.

5.5.6 Electronic methods should not be used if participants, for any reason, indicate a lack of comfort with electronic media.

5.5.7 Such tools may be reviewed and approved by EC before implementation.

5.6 Specific issues in Clinical trials

There may be additional requirements for informed consent for clinical trials as specified by CDSCO. See section 7 for further details.

5.7 Waiver of consent

The researcher can apply to the EC for a waiver of consent if the research involves less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants Box 5.2.

Box 5.2 Conditions for granting waiver of consent

The EC may grant consent waiver in the following situations:

- research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/data;
- certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

5.8 Re-consent or fresh consent

Re-consent is required in the following situations when:

- new information pertaining to the study becomes available which has implications for participant or which changes the benefit and risk ratio;
- a research participant who is unconscious regains consciousness or who had suffered loss of insight regains mental competence and is able to understand the implications of the research;
- a child becomes an adult during the course of the study;
- research requires a long-term follow-up or requires extension;
- there is a change in treatment modality, procedures, site visits, data collection methods or tenure of participation which may impact the participant's decision to continue in the research; and
- there is possibility of disclosure of identity through data presentation or photographs (this should be camouflaged adequately) in an upcoming publication.
- the partner/spouse may also be required to give additional re-consent in some of the above cases.

5.9 Procedures after the consent process

5.9.1 After consent is obtained, the participant should be given a copy of the PIS and signed ICF unless the participant is unwilling to take these documents. Such reluctance should be recorded.

5.9.2 The researcher has an obligation to convey details of how confidentiality will be maintained to the participant.

5.9.3 The original PIS and ICF should be archived as per the requirements given in the guidelines and regulations.

5.10 Special situations

5.10.1 Gatekeepers

Permission of the gatekeepers, that is, the head/leader of the group or culturally appropriate authorities, may be obtained in writing or audio/video recorded on behalf of the group and should be witnessed.

5.10.2 Community consent

In certain populations, the community plays an important role in the consent process. Some participants may not participate in the research unless the community's consent is available. There may be situations when individual consent cannot be obtained as it will change the behaviour of the individual (see section 8 for further details). In such situations community consent is required. When permission is obtained from an organization that represents the community, the quorum required for such a committee must be met. For example, in a village panchayat the number of members ordinarily required to conduct a meeting must be present while giving consent. Individual consent is important and required even if the community gives permission.

5.10.3 Consent from vulnerable groups

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. The list of vulnerable populations/communities is given in Box 6.2.

5.11 Consent for studies using deception

Some types of research studies require deception due to nature of research design. A true informed consent may lead to modification and may defeat the purpose of research. Such research may be carefully reviewed by the EC before implementation.

5.11.1 True informed consent in studies involving deception is difficult due to the nature of research. A two-step procedure may be required comprising an initial consent and a debriefing after participation.

5.11.2 The possibility of unjustified deception, undue influence and intimidation should be avoided at all costs. Although deception is not permissible, approval may be taken from the EC in circumstances where some information requires to be withheld for validation until the completion of the research.

5.11.3 In such instances, an attempt should be made to debrief the participants/communities after completion of the research.