IEC Karnataka Health Promotion Trust

(KHPT Letter head and details)

Informed Consent Form

Informed Consent Process:

Informed consent protects the individual's autonomy to freely choose whether or not to participate in the research. The process involves three components – **providing relevant information to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation**. Informed consent should explain medical terminology in simple terms and be in a language that the participant understands.

The informed consent document (ICD), which includes patient/participant information sheet (PIS) and informed consent form (ICF) should have the required elements (see Table 1 for further details) and should be reviewed and approved by the EC before enrolment of participants. For all biomedical and health research involving human participants, it is the primary responsibility of the researcher to obtain the written, informed consent of the prospective participant or legally acceptable/authorized representative (LAR). In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.

Requisites

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 to give consent.
2. The consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements.
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.
4. It is mandatory for a researcher to administer consent before initiating any study-related procedures involving the participant.
5. It is necessary to maintain the privacy and confidentiality of participants at all stages.
6. The language should not only be scientifically accurate and simple but should also be sensitive to the social and cultural context of the participant.
7. 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 enrol in the research.

Table 1: Essential and Additional Elements of an Informed Consent Document

An informed consent form must include the following:	In addition, the following elements may also be required, depending on the type of study:
1. Statement mentioning that it is research 2. Purpose and methods of the research in simple language	1. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is

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)	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 pretest- 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 mentioned. iii right to prevent the 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.

Section A-Participant Information Sheet (PIS)

Based on the ICMR guidelines (2017), a Participant Information Sheet (shared on KHPT letterhead); and Consent Seeking should cover the following elements in simple local language that the participants of the research can comprehend. While the information shared must be comprehensive, care should be taken to not make it too lengthy and time-consuming such that it defeats the purpose of "informing" the participants as they might not go through it in full -

1. Statement mentioning that it is a research study that the participant has been approached for.
2. Title of the study, the purpose of the study and how it will be conducted to be explained in simple steps (i.e., explanation of the methodology with specific points where their participation is requested).
3. The kind of data to be collected and how it will be collected (interviews, FGDs, etc.). How will these be recorded should be explicitly mentioned.
4. Expected duration of the participation and frequency of contact (example, pre and post – test and at the time of sharing of data and information at the end of the study).
5. Anticipated / expected benefits to the participant, community or others that might reasonably be expected as an outcome of research.
6. Any foreseeable risks (Physical/social/psychological/discomfort/ financial/any other) to the participants resulting from participation in the study (example, they may need to take out time from their schedule specifically for the purpose and the assurance that this will be done as per their convenience).
7. Communication regarding voluntariness and autonomy regarding participation in the study and to right to withdraw from the study at any time without loss of potential benefits to which the participant would otherwise be entitled by being part of the target population or is already receiving as a result of a previous engagement in a connected study.
8. Extent to which confidentiality of records can be maintained, the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.
9. Immediate use of data / information collected and form in which data / information will be shared with others (example, anonymous with no identifiable markers, or just aggregate data, etc.). Any anticipated future use of data or information thus collected (publications / secondary research / advocacy / etc.).
10. Payment/reimbursement for participation and incidental expenses, if any, depending on the type of study.
11. Possibility of any compensation if any injury / harm anticipated as a result of participation (loss in wages, loss of job, etc.).
12. Post – research plan and benefit sharing. Communication of outcomes of study to the participants, publication plans and assurance of anonymity. If any identifiable information requires to be used (such as a photograph), written consent for the same to be sought, even of faces or other identifiable markers to be blurred.

13. The identity of the research team and ERB members (Principal Investigator, Co – Principal Investigator; and Chairperson and Member Secretary of the ERB) with contact numbers with addresses. KHPT office email and phone numbers can be the ones shared. The participants should be informed that they can contact the ERB members in case of any issue.

(B)

KHPT letter head
(letter head and details)

(Sample template, can be adapted to specific needs and language)

(Oral communication – after PIS or information in any other format has been shared)

Hello, my name is, (name and designation of researcher taking consent), and I work for KHPT. KHPT's work focusses on the well - being of pregnant women, new mothers, infants and children in the first five years of their life. If you want more information about our work, you can visit our website https://KHPT.org/ (OR share a brochure).

Today I am here as I am doing research with my team on a study titled, _____. Detailed information about the study has been shared with you via a what's app voice message / pamphlet / (state mode of sharing participant information format). Have you read the sheet / heard the voice message?

(If no) – please take the time to do so. I will wait here / come back / call back another day (as relevant). Can you tell me when I can come back / call you back (as relevant)?

(If yes) - I am here / talking to you personally; to help you understand the study and how your participation can help us (share the details of the study orally as shared in the PIF in simple local language).

(Continue) You can take time to make your decision and you can speak to anyone you feel comfortable with about the study. Is there anything that I have shared with you that you would like to understand better? Can you please share that with me so that I can clarify your doubts?

(The researcher should also ask questions to ensure that the potential participant has understood the details. These could be, "Can you tell me what this study is about?" or "Why we have approached you to participate?", "Do you know you can say no to participation or withdraw at any stage?" and so on).

This study has been reviewed by the KHPT Ethics Review Board who are helping us do the study in the best way possible. Their Names and numbers are (Chairperson and Member secretary). Feel free to contact them if you have any problems while participating in the study. Share how you will ensure privacy (at the time of the interview), confidentiality (of information) and their identity (anonymity).

(If potential participant agrees to participate, inform them that they would like to confirm participation using the informed consent form or they should reply on technology enabled confirmation of consent).

(C)

(Form 2)

INFORMED CONSENT FORM (ICF)

(a copy remains with the participant and one with KHPT)

Name of participant _____

(name to be given an identification number to protect anonymity and confidentiality or omit if not needed. Can be replaced with phone number).

Name of study:

I have understood the study as explained to me and I have also heard on the audio / video message / read on the pamphlet/_____(state the participant information format used to share information about the study with the participants). I voluntarily agree to participate in this study for the said duration. I understand that I can withdraw my participation at any point without consequences and understand the potential risks and benefits along with extent of confidentiality possible to be given and future anonymous use of data thus generated as part of this study for research purposes for the benefit of more people and for science in general (read it out if required).

Name of the Organization: KHPT

Address and phone numbers: Details

Name of the Principal Investigator:

Name of the Co – Principal Investigator:

Signature of Participant _____

Date _____

If illiterate, take witness signature:

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

Name of witness_____ Thumb print of participant

Signature of witness _____

Date _____

Statement by the researcher taking consent -

I have shared the information about the study in a Participant Information Format and I have shared the same orally to the potential participant, and to the best of my ability made sure that the participant understands what is the study is about and her role as a participant. I confirm that the participant was given an opportunity to ask questions about the study, and that these were answered to the best of my ability. I confirm that the individual has not been coerced directly or indirectly into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____