ANNEXURE: 04 **AF/IEC/04/08/V7.3**

Guidelines for reviewing Participant Information Sheet and Informed Consent Document

The following points should be considered while reviewing the Participant Information Sheet and Informed Consent Document

1) Participant Information Sheet Process

- The EC Members should check whether the Participant Information Sheet and Informed Consent Document are as per the norms provided to the Principal Investigator (AF/EC/03/08/V7.3). The Participant Information Sheet (PIS) and Informed Consent Document (ICD) should be congruent with the Application and the research study.
- To see whether the information in the consent form is a reflection of Investigator's communication with the study participant.
- Final comprehensive information of the study may also be given to the participants.
- Information provided in Participant Information Sheet is in simple language (easily understood by lay person), with no scientific jargon and yet complete and updated. Informed consent documents should be written using language at the reading level and technical level of the participant.
- Consent document is written at the 8th grade reading level.
- Because research participants come from a variety of backgrounds and educational levels and are frequently under physical and emotional stress, it is important that Participant Information Sheet/consent form is easy to understand. If a medical term is essential, lay language definition is included . .
- No informed consent, whether oral or written, may include any language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- Investigator/Co-Investigator has to obtain consent from the potential participants.
- The individual taking the consent should be well versed, sufficiently trained and knowledgeable about the study to answer any questions or appropriately refer questions that may exceed their expertise put forth by the potential study participants.
- The individual obtaining consent can unintentionally influence a research participants decision to participate in research, hence every effort should be taken to avoid undue influence.
- Maintaining privacy and the place/setting in which the consent is obtained is of paramount importance. The consent process should be conducted individually and in areas where the discussion is not overheard, there is no peer pressure and or/inattention and no unwanted stress or anxiety.

- The timing of the consent process may have a negative impact on the potential research participant's ability to make a considered decision.
- All research participants must be given the Participant Information Sheet and the Informed Consent Document to take it home (If they desire's so)to discuss it with their family members, doctor and friends. Allowing the research participants sufficient time may improve the quality of the informed consent process. In case of studies pertaining to delivery/labor, informed consent should be obtained in the prenatal visit and reconsent may be taken.
- Investigator, study co-ordinator, social worker or any other team member of the research study should sit face-to-face with the potential participant read/discuss the Participant Information Sheet/Informed Consent Document

Telephone surveys/interveiw

- Describe how personal information will remain confidential. In the case where the data collected contains identifying information (e.g., interview tapes, contact information for follow up studies, clinical history with age and name and other identifiable information), describe with whom, for how long, how the data will be stored, and that when the data is no longer required the data will be appropriately destroyed. If the data are anonymous, this statement may be omitted.

  All records identifying the participants will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. The study doctor and research team will use personal information about you to conduct this study. This may include your name, address, medical history and information from your study visits. However, this personal information is not included in the study data that will be forwarded to the sponsor or sponsor representatives. You will be identified by a coded number in any reports of publications produced from this study (study data).

  This is important in studies like in Reproductive tract infections, gene studies etc.
- Describe who has access to the data, where the data is and how it will be stored securely.

  To confirm that the study data collected about you is correct and related to you, selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. **By signing this document, you are authorizing such access.**

2) Informed Consent Process

The actal **process of informed consent** should:

- Give the participants significant **information** about the study.
- Make sure the participants have **enough time** to carefully read and consider all options.
- **Answer all questions** of the participants before making decision to participate.
- Explain **risks or concerns** to the participants**.**

- Make sure that all information is **understood and satisfies the participants**.
- Make sure the participants understand the study and the consent process.
- Obtain **voluntary** informed **consent** to participate.
- Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
- Consent should be **informally verified on a continuing basis.**
- **Continue to inform** the participants throughout the study.
- **Continue to re -affirm** the **consent/assent** to participate throughout the study.
- CRC should write the entire narration of the complete informed Consent Process.
- **Procedures or methods** used in the informed consent process for recruitment of study participants include:A consent form
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)
- Internet information
- Instruction sheets
- Audio-visual presentations
- Charts, diagrams or posters
- Discussions
- Consultation with others
- Duration of sample storage and its disposal

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words, remove technical jargon and medical terms.
- Try to use correct basic grammar and form.
- Use "gene **transfer**" instead of "gene **therapy**" (less implied effectiveness).
- Use"**agent**" instead of "**drug**" or "**medicine** " (less implied effectiveness).

  Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness)

ANNEXURE:05 **AF/IEC/05/08/V7.3**

Participant Information Sheet

Title of Project:_____
Principal Investigator: Name,
Designation,
Contact details_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research study about?
2. What information is known about this type of research study?

3. Why is this research study being done?
4. Who can take part in this research study?
5. How many participants will be included for this research study?
6. What do you have to do if you agree to take part in the research study?
7. **What are the possible benefits to you by being in the research study?**
8. How will the research study be done?
9. What are the tests that will be performed on the participant/ biological sample?
10. **How long will you be in the research study?**
11. **How long the biological samples will be stored and how will it be disposed?**
12. Under what conditions will your Participation in the study be terminated?
13. What are the possible risks and inconveniences that you may face by being in the research study?
14. What happens if you are injured since you took part in this research study?
15. What are the other treatment options/alternatives to participation?
16. What will happen if you change your mind about participation in this research study?
17. How will your privacy and confidentiality be maintained?
18. Will you have to bear any Expenses or Costs by participating in the research study?
19. Whom do you call if you have questions or problems?
    a. Research related
    b. Regarding rights as a Participant

Please note that some questions may not be applicable to your research study, hence can be marked as Not Applicable, example Q.12 is applicable for clinical trials, Q.10 may not be applicable for basic research studies wherein the biological samples are taken at a point time.

Please contact the researchers listed below to:

Obtain more information about the study

Ask a question about the study procedures or treatments

Dr. …….

Scientist.....

Depatment.....

Phone…..

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

Name of the Member Secretary

Ethics Committee,KLE Academy of Higher Education and Research
JNMC Campus Nehrunagar Belagavi 590010
Tel.No.: 0831-2470400
Fax No.: 0831-2493099
Email : kleclinicalresearch@gmail.com
Time to contact- Office Hours

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

ANNEXURE: 06 **AF/IEC/06/08/V7.3**

Informed Consent Form

I_____have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of Impartial witness/Legal Authorised Representative (wherever relevant) with date	**Signature/Thumb impression of Study Participant with date**
Name of the Witness	Name of the Study Participant
Signature of Principal Investigator with date Name of the Principal Investigator	Signature of Person administering the consent with date Name of the Person administering the consent

ANNEXURE: 07 **AF/IEC/07/08/V7.3**

Informed Consent Form
(For future use of stored samples)

I_____ give/do not give permission to preserve my samples to be used for any extension / modification of this study.

If any other studies planning to use these left over stored samples, are decided in future, with the appropriate permission of the Ethics Committee.

I hereby give my consent willingly for use of my samples for future studies as mentioned above.

For Limited or non readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of Impartial witness with date

Name of the Witness

Signature/Thumb impression of Study Participant with date

Name of the Study Participant

Signature of Principal Investigator with date

Name of the Principal Investigator

Signature of Person administering the consent with date

Name of the Person administering the consent

ANNEXURE: 08 **AF/IEC/08/08/V7.3**

Assent Form

I ……have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my assent willingly to participate in this research study.

For Limited or non readers: (Illiterate participants) I have witnessed the assent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Signature of Impartial witness with date

Signature/Thumb impression of Study Participant with date

Name of the Witness

Name of the Study Participant

Signature/Thumb impression of Mother/Father with date

Name of the Parent

Signature of Principal Investigator with date

Name of the Principal Investigator

Signature of Person administering the assent with date

Name of the Person administering the assent