



Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road, New Delhi – 110001
Date : 16-May-2023

FORM CT-03

(See rules 17 and 18)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No. **EC/NEW/INST/2023/RJ/0279**

The designated authority hereby registers and permits INSTITUTIONAL ETHICS COMMITTEE SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE, SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE HH GARDENS power house road, City-Sri Ganganagar, District-Sri Ganganagar - Rajasthan - 335001 Contact No.: 01542440102 Fax No.: to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date : 16-May-2023

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by ANU NAGAR
Date: 2023.05.16
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Designated Registration Authority
Stamp



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Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
 Red Cross Road, New Delhi – 110001
 Date : 24-May-2023

Composition of the Ethics Committee:

S.No.	Name of Member	Qualification	Role/Designation in EC
1	Dr. PARVEEN KUMAR	Other (MD HOMEOPATHY)	Chair Person
2	Dr. MANU BATRA	BDS (MDS -Public Health Dentistry)	Member Secretary
3	Dr. ANANT PRAKASH DADHICH	MBBS (MD - Pharmacology and Therapeutics)	Basic Medical Scientist
4	Dr. Rajnish Aggarwal	BDS (MDS PROSTHODONTICS)	Clinician
5	Dr. Punam Bajaj	BSc (MA - Sociology)	Social Scientist
6	Mr. SURENDER SINGH BHANOT	LLB (CIVIL)	Legal Expert
7	Ms. Taranjeet Kaur	BA (Not Applicable)	Lay Person

BISWABANDAN SENAPATI
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 BISWABANDAN SENAPATI
 Date: 2023.05.24 12:42:27
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 (B. Senapati)
 Deputy Secretary to Govt. of India



INSTITUTIONAL ETHICS COMMITTEE
SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE
HH GARDENS, KARNI ROAD
SRI GANGANAGAR, INDIA

IEC GENERAL INFORMATION

This document
for
Institutional Ethics Committee
of
SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE
is
Prepared by
Dr. Dinesh Kumar Verma
Department of Oral and Maxillofacial Surgery
According to and adapted from
Indian Council of Medical Research guidelines

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Composition of IEC

The IEC will consist of 8-12 members and a minimum of 5 members will form the quorum for taking a decision regarding any submitted research.

The composition will be as follows

1. Chairperson
2. Member secretary
3. One – two persons from basic medical science area
4. One- two clinicals
5. One legal expert or retired judge
6. One social scientist / representative of non governmental agency
7. One lay person from the community
8. One Pharmacologist

Responsibilities of the IEC

1. To protect and safeguard the dignity, rights, safety and well being of all actual or potential research participants.
2. To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethic consideration.
3. To provide advise to the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research.

Consent letter for members of IEC

To

The Director

Surendera Dental College and Research Institute

HH Gardens

Karni Road

Sri Ganganagar

Rajasthan- 335001

Sub: Consent to be a member of IEC, SDCR&I

Sir,

I accept the invitation to become a member of IEC of Surendera Dental College and Research Institute. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing to publicize my full name, profession and affiliation. I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC. I shall not keep any literature or study related document with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel. I herewith enclose my CV.

Thanking You,

Yours sincerely,

Signature -----

Name of Member.-----

Date Address and Telephone No:

APPLICATION PROCEDURE FOR ETHICAL CLEARANCE

All Principal Investigators are requested to submit new project proposals for the review of Ethics Committee to The Institutional Ethical Committee (IEC), room no 2, Block- A, Surendera Dental College & Research Institute in the prescribed format along with documents according to the list of documents.

1. A cover letter (**Annexure 1**),
2. Principal Investigator form - Form I (**Annexure 2**)
3. Review form – Form II (**Annexure 3**). Fill only the sections required to be filled by Principal Investigator
4. Decision Letter – Form III (**Annexure 4**). Fill only the sections required to be filled by Principal Investigator
5. Research Protocol :
 - a. Introduction: Should clearly identify the need for the present research (why it is important to conduct this research). Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory, animal and human research
 - b. Aims and Objectives:
 - c. Materials and methods:
 1. Participant recruitment procedures
 2. Procedure for seeking and obtaining informed consent
 3. Inclusion and exclusion criteria for entry of participants.
 4. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, **experimental, pilot, randomized, blinded** etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any.
 5. In case the research involves a study product (such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)
 6. Plan to withdraw or withhold standard therapies in the course of research.
 7. For research involving more than minimal risk, an account of management of such risk or injury
 8. Proposed compensation and reimbursement of incidental expenses, if planned
 9. A statement of maintaining privacy and confidentiality of the study participants

10. A statement of agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials
 11. Details of Funding agency/ Sponsors and fund allocation, if any
 12. A statement on conflict-of-interest (COI), if any

 13. Plan for statistical analysis of the study.
- d. References: Appropriate references
 - e. Annexures (if any): example - Case report forms, questionnaires, handouts intended for research participants
 - f. Informed consent form in local language and English (**Annexure 5**)
 - g. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/
authority like Drug Controller General of India (DCGI)
 - h. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
 - i. All previous IEC 's decisions(e.g., those leading to a negative decision or modified protocol) by other ECS or regulatory authorities for the proposed study(whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.
 - j. Summary of research protocol in non-technical language.
6. Consent form (Annexure 5). The researcher may choose the appropriate consent form from the forms provided in the annexure 5.
 7. **Fees:** A non-refundable fees of INR 200 will be taken along with the submission of the study protocol.

The decision on the study protocol will be intimated through e-mail after review by the reviewer and conduct of next EC meeting.

Annexure 1: Covering Letter

Application for Ethical Review of Biomedical Research Proposal

To

The Chairman

Institutional Ethical Committee

Surendera Dental College and Research Institute

HH Gardens

Karni Road

Sri Ganganagar

Rajasthan- 335001

Date:

Full name of applicant : _____

Designation:

Complete Postal Address:

Mob No:

e-mail:

Title of Project:

Sir,

I am submitting my research protocol for approval by the Ethical Committee. I have submitted the required list of documents in the prescribed format along with my application.

Thanking you,

Yours Sincerely

Signature (Principal Investigator)

1.Type of Study : Epidemiological <input type="checkbox"/> Basic Sciences <input type="checkbox"/> Animal studies <input type="checkbox"/> Clinical: Single center <input type="checkbox"/> Multicentric <input type="checkbox"/> Behavioral <input type="checkbox"/>		
2. Status of Review: New <input type="checkbox"/> Revised <input type="checkbox"/>		
3. Clinical Trials: Drug /Vaccines/Device/Herbal Remedies : i. Does the study involve use of : Drug <input type="checkbox"/> Devices <input type="checkbox"/> Vaccines <input type="checkbox"/> Indian Systems of Medicine/ Alternate System of Medicine <input type="checkbox"/> Any other <input type="checkbox"/> NA <input type="checkbox"/>		
ii. Is it approved and marketed In India <input type="checkbox"/> UK & Europe <input type="checkbox"/> USA <input type="checkbox"/> Other countries, specify <input type="checkbox"/>		
iii. Does it involve a change in use, dosage, route of administration? If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained? If yes, Date of permission :	Yes Yes	No No
iv. Is it an Investigational New Drug? If yes, IND No:	Yes	No
a). Investigator's Brochure submitted	Yes	No
b). <i>In vitro</i> studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/>		
e). Are you aware if this study/similar study is being done elsewhere ? If Yes, attach details	Yes	No
4. Description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale : ATTACHED SYNOPSIS COPY		
5. Privacy and confidentiality i. Study involves - Direct Identifiers <input type="checkbox"/> Indirect Identifiers/coded <input type="checkbox"/> Completely anonymised/ delinked <input type="checkbox"/>		
i. Confidential handling of data by staff	Yes	No

6. Use of biological/ hazardous materials	Yes	No
i. Use of fetal tissue or abortus		
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iii. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad ?	Yes	No
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? b) Sample will be sent abroad because (Tick appropriate box): Facility not available in India <input type="checkbox"/> Facility in India inaccessible <input type="checkbox"/> Facility available but not being accessed. <input type="checkbox"/> If so, reasons...	Yes	No

7. Consent : *Written Oral Audio-visual
i. Consent form : (tick the included elements)

- | | | | |
|--|--------------------------|---|--------------------------|
| Understandable language | <input type="checkbox"/> | Alternatives to participation | <input type="checkbox"/> |
| Statement that study involves research | <input type="checkbox"/> | Confidentiality of records | <input type="checkbox"/> |
| Sponsor of study | <input type="checkbox"/> | Contact information | <input type="checkbox"/> |
| Purpose and procedures | <input type="checkbox"/> | Statement that consent is voluntary | <input type="checkbox"/> |
| Risks & Discomforts | <input type="checkbox"/> | Right to withdraw | <input type="checkbox"/> |
| Benefits | <input type="checkbox"/> | Consent for future use of biological material | <input type="checkbox"/> |
| Compensation for participation | <input type="checkbox"/> | Benefits if any on future commercialization | <input type="checkbox"/> |
| Compensation for study related injury | <input type="checkbox"/> | eg. genetic basis for drug development | |

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI Nurse/Counsellor
 Research staff Any other

8. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
--	-----	----

9. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
--	-----	----

ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>	Yes	No
--	-----	----

iii. Is there a benefit a) to the subject ? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		
--	--	--

10. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
---	-----	----

ii. Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input type="checkbox"/>	Yes	No
--	-----	----

iii. Is there a plan for interim analysis of data?	Yes	No
--	-----	----

vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long ?	Yes	No
---	-----	----

11. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes	No
--	-----	----

12. Is there compensation for injury? If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance company <input type="checkbox"/> by any other <input type="checkbox"/>	Yes	No
--	-----	----

13. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No
---	-----	----

Checklist for attached documents:

- Project proposal – 2 Copies (1hard/1soft on CD)
- Patient information sheet
- Informed Consent form
- Investigator’s brochure for recruiting subjects
- Copy of advertisements/Information brochures
- Copy of clinical trial protocol and/or questionnaire
- Institutional Animal Ethics Committee clearance
- CPCSEA clearance, if any
- HMSC/DCGI/DBT/BARC clearance if obtained

Place:
PI/Collaborator
Date:

Signature & Designation of PI/Co-

Annexure-III (Reviewer's form)

Institutional Ethics Committee Review Form

Serial No of IEC (to be filled by IEC Office):

-----To be filled by Investigators-----

Proposal Title:

Principal Investigator:

Co-investigator: 1.
2.
3.

Supporting Agency: ICMR/ non ICMR

If non ICMR, name of agency:

-----To be filled by reviewer-----

Project Status: New Revised

Review: Regular Interim

Date of Review:

1. Research Design

- i. Scientifically sound enough to expose subjects to risk Yes No
- ii. Relevant to contribute to further knowledge Yes No
- iii. Of national importance Yes No

2. Risks

- a. Is there physical/social/psychological risk/discomfort? Yes No
- b. Is the overall risk/benefit ratio Acceptable Unacceptable

3. Benefits

Direct: Reasonable Undue None

Indirect: Improvement in science/knowledge

Any other

4 Subject selection :

- i Inclusion / exclusion criteria addressed? Yes No
- ii Vulnerable subjects (woman, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected ? Yes No
- iii. Special group subjects (captives, students, nurses & dependant staff) adequately protected? Yes No

Privacy & Confidentiality maintained?

Yes No

Patient Information Sheet:

Consent form components addressed adequately?

Adequate Yes Inadequate No

8. Compensation, (if applicable) addressed adequately?

Yes No

9. Is there a Conflict of Interest?

Yes No

If yes,

Acceptable Unacceptable

10. Budget:

Appropriate Inappropriate

11. Decision of review

Recommended

Recommended with suggestions

Revision

Rejected

Any other remarks/suggestions:

Reviewers names and Signatures

Annexure-IV (Decision form)

Communication of Decision of the Institutional Ethics Committee (IEC)

(Fields 1,2 and 3 to be filled by investigators)

IEC No:

1. Protocol title
2. Principal Investigator:
3. Name & Address of Institution:
<input type="checkbox"/> New review <input type="checkbox"/> Revised review <input type="checkbox"/> Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC/ IRB: <input type="checkbox"/> Recommended <input type="checkbox"/> Recommended with suggestions <input type="checkbox"/> Revision <input type="checkbox"/> Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Please note *

- **Inform IEC immediately in case of any Adverse events and Serious adverse events.**
- **Inform IEC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC.**
- **Members of IEC have right to monitor the trial with prior intimation.**

**Principal
SDCRI**

**Chairman
IEC**

**Member Secretary
IEC**



Annexure – V (various consent forms)

Informed Consent Form Template for

Clinical Studies

(This template is for either clinical trials or clinical research)

(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
 - square brackets indicate where specific information is to be inserted
 - bold lettering indicates sections or wording which should be included
 - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE



Surendera Dental College & Research Institute, Sri Ganganagar

[Name of Principle Investigator]

[Informed Consent form for _____]

Name the group of individuals for whom this informed consent form is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is ".....")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, “mosquitoes help in spreading the disease” rather than “mosquitoes are the vectors”. Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

- **Example of question to elucidate understanding:** Do you know why we are asking you to take part in this study? Do you know what the study is about?

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

- **Examples of question to elucidate understanding:** If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

- 1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
- 2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- 3) explain the known experience with this drug
- 4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to...." instead of "we would like to ask you to....".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

- 1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example: Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting

and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

If the protocol is for clinical research:

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take aboutthis much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- After one week, you will come back to the clinic for a blood test. This will involve....)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for ___ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- **Examples of question to elucidate understanding:** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

- **Examples of question to elucidate understanding:** *Do you understand that, while the research study is on-going, no-one may know which medicine you are receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example: We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

- **Examples of question to elucidate understanding:** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.)

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- **Example of question to elucidate understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)

OR

(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given....)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- **Example of question to elucidate understanding:** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

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.

Print name of witness _____

AND

Thumb print of participant

Signature of witness _____

Date _____



Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1.**
- 2.**
- 3.**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

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

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year



***Informed Parental Consent Form Template for
Research Involving Children (Clinical Studies)***

(This template is for either clinical trials or clinical research)

(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
 - square brackets indicate where specific information is to be inserted
 - bold lettering indicates sections or wording which should be included
 - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE



Surendra Dental College & Research Institute, Sri Ganganagar

[Name of Principal Investigator]

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X)

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are, and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country.)

I am going to give you information and invite you to have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose

Explain the problem/research question in lay terms which will clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, “mosquitoes help in spreading the disease” rather than “mosquitoes are the vectors”. Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

(Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine).

Type of Research Intervention

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

(An injection OR a series of three injections OR taking a vaccine orally, a biopsy).

Participant selection

State clearly why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

(The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can't assume that the vaccine will be as effective on young children unless we test it on children

We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.)

- **Example of question to elucidate understanding:** *Do you know why your child has been identified as a potential research participant? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.)

- **Examples of question to elucidate understanding:** *If you decide that you do not want your child to take part in this research study, do you know what your options for him/her are? Do*

you know that you do not have to accept that your child takes part in this research study? Do you have any questions?

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

- 1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.
- 2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- 3) explain the known experience with this drug
- 4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(The ABX vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exist. While the current vaccine protects only 60% of people who take the vaccine the new one protected more than 80% of the people. The new vaccine also protected for a longer time period. We want to compare those two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.

The drug is made by Company AB, who is working with a local hospital to have it tested. Its called a _____type of drug because it helps part of the blood to_____. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.)

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to...." instead of "we would like to ask you to....".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

(Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.

One group will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was given. This information will be in our files, but we will not look at these files until after

the research is finished. This is the best way we have for testing vaccines without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medicines or treatment is doing, we will find out which vaccine your child is getting and make changes.)

2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

(A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

(If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a “rescue medicine.”.)

B. Description of the Process

Describe the process on a step-by-step basis.

(You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child's arm. This will be tested for the presence of substances that help your child's body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising but this will disappear in a few days.

In the next visit, your child will be given either the test vaccine or the vaccine that is currently being used for malaria in this region. Neither you nor we will know, until later in the study, which vaccine your child was given. The vaccine will be given by a trained healthcare worker. After the vaccine, we ask that you and your child stay at the clinic for 30 minutes so that the healthcare worker can observe any immediate changes in the child's mood, and if swelling occurs around the injection site. We will give you and your child juice and something small to eat.

We will ask your child's physician to give us the details of your child's health and illness related information. If you do not wish us to do that, please let us know. However, because your child's health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given....)

In case of a clinical research:

Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Your child will receive the treatment for his/her condition according to national guidelines, etc. The sample will be taken using a local anesthesia which means that only the part of your child that we are

taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn't feel pain, etc.)

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ___ years, when the research is completed.

Duration

Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

(The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days, for ___ (number of) hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year).

- **Examples of question to elucidate understanding:** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at anytime and ask to see [name of nurse, doctor, researcher].

We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

(By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that _____may happen as a result of taking this drug.

While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide your child with_____. [explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.]

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

(By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.)

- **Examples of question to elucidate understanding:** *Do you understand that, while the research study is on-going, no-one may know which medicine your child is receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that your child may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not your child is in the research study? Etc. Do you have any questions?*

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(If your child participates in this research, he/she will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefit for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(You will not be provided any incentive to take part in this research. However, you will be reimbursed with - provide a figure if money is involved - for your lost time and travel expense.)

- **Examples of question to elucidate understanding:** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your and your child's travel costs and your time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done

through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- **Example of question to elucidate understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you and/or your child will remain confidential? Do you have any questions about them?*

Sharing of the results

Your plan for sharing the information with the participants and their parents should be provided. If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

(The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research).

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

(You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this Centre will be affected in any way.)

Alternatives to participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given....)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

(If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]

PART II: Certificate of Consent

Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

(I have been invited to have my child participate in research of). **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

Print Name of Participant _____

Print Name of Parent or Guardian _____

Signature of Parent or Guardian _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

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

Print name of witness _____

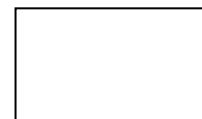
AND

Thumb print of parent

Signature of witness _____

Date _____

Day/month/year



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

- 1.**
- 2.**
- 3.**

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

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

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

An Informed Assent Form will _____ OR will not _____ be completed.

Assent Form will _____ OR will not _____ be completed.



***Informed Consent Form Template for
Consent for Storage and Future Use of
Unused Samples***

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. In this template:
 - square brackets indicate where specific information is to be inserted
 - bold lettering indicates sections or wording which should be included
 - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE



Surendera Dental College & Research Institute

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

<input type="checkbox"/> I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
<input type="checkbox"/> I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
<input type="checkbox"/> I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

<input type="checkbox"/> I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]
<input type="checkbox"/> I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
<input type="checkbox"/> I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

<input type="checkbox"/> I want my identity to be removed from my (TYPE OF SAMPLE) sample.
<input type="checkbox"/> I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant _____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

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.

Print name of witness _____

AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1.**
- 2.**
- 3.**

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

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

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

The review process:

The review will be done by primary reviewer and the protocol of the project with informed consent and patient information sheet, advertisements or brochures, if any, will be circulated to all the other members.

The ethical review will be done in formal meetings.

The committee will meet at regular intervals and will not keep a decision pending for more than 3 months.

The decision making process:

The IEC will meet periodically (at least once every month) for reviewing new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. The following points will be considered while doing so :

1. The decision will be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary will communicate the decision in writing to the PI.
2. If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting, and it will also be recorded in the minutes.,
3. If one of the members has her/his own proposal for review or has any COI then s/he will withdraw from the IEC while the project is being discussed
4. A negative decision will always be supported by clearly defined reason
5. The IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
6. The discontinuation of a trial will be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
7. In case of premature termination of study, notification will include the reasons for termination along with the summary of results conducted till date.
8. The following circumstances require the matter to be brought to the attention of IEC:
 - a. any amendment to the protocol from the originally approved protocol with proper justification;
 - b. serious and unexpected adverse events and remedial steps taken to tackle them;
 - c. any new information that may influence the conduct of the study.
9. If necessary, the applicant/investigator will be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or interest groups can be invited during deliberations to offer their viewpoint.
10. Subject experts may be invited to offer their views, but will not take part in the decision making process. However, her / his opinion will be recorded.
11. Meetings will be minuted, approved and signed by the Chairperson/ alternate Chairperson/ designated member of the committee.

Meeting requirements

- * All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.
- * Additional review meetings can also be held with short notice as and when required.
- * Meetings will be planned in accordance with the need of the work load.
- * Member will be given 10 days time in advance to review study proposals and the relevant documents.
- * Minutes of the IEC meetings, all the proceedings and deliberation will be documented.
- * Signatures of all the members who have participated in the meeting will be obtained on the minutes of the meeting document.
- * Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.
- * Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

Quorum requirements

1. Minimum 5 members are required to compose the quorum for full review
2. No quorum should consist entirely of members of one profession.
Quorum will include at least one member as non scientific(lay person),
3. For expedited review, minimum of 3 members are required of which one must be expert in the area of research proposal.

Review category

Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations :

- i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

- i. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
- ii. When interviews involve direct approach or access to private papers.

Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories :
 - a. Clinical studies of drugs and medical devices only when -
 - i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population
 - or
 - ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
4. Research involving clinical materials (data, documents, records, or specimens) that have been

collected for non-research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation. When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

- i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
- ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of dcgi;
- iii. Only if the local iec reviews the protocol since institutional responsibility is of paramount importance in such instances.
- iv. If data safety monitoring board (dsmb) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

- i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
- ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
- iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
- iv. Protection must be ensured so that only minimal additional risk is imposed.

- v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.
- vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
- vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

1. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;
2. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;
3. From neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
4. Prospective collection of biological specimens for research purposes by noninvasive means.
For instance:
 1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
 2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
 3. Excreta and external secretions (including sweat);
 4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
 5. Placenta removed at delivery;
 6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice.

Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
2. Weighing or testing sensory acuity;
3. Magnetic resonance imaging;
4. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow,
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. *Research involving clinical materials* (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. *Collection of data from voice, video, digital, or image recordings made for research purposes.*

e. *Research on individual or group characteristics or behavior* not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

MONITORING

Once IEC gives a certificate of approval it will be the duty of the IEC to monitor the approved studies. The IEC will visit the site of research as and when deemed necessary to identify any violation of ethical aspects of the research.

RECORD KEEPING

All documentation and communication of an IEC are to be dated, filed and preserved for 3 years. Strict confidentiality is to be maintained during access and retrieval procedures. The following records will be maintained:

- a. The Constitution and composition of the IEC;
- b. Signed and dated copies of the latest the curriculum vitae of all IEC members with records of training if any;
- c. Standing operating procedures of the IEC;
- d. National and International guidelines;
- e. Copies of protocols submitted for review;
- f. All correspondence with IEC members and investigators regarding application, decision and follow up;
- g. Agenda of all IEC meetings;
- h. Minutes of all IEC meetings with signature of the Chairperson;
- i. Copies of decisions communicated to the applicants;
- j. Record of all notification issued for premature termination of a study with a summary of the reasons;
- k. Final report of the study including microfilms, cds and Video recordings.

GENERAL GUIDELINES

I. INFORMED CONSENT PROCESS

1. Informed Consent of Participants : For all biomedical research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant/ Patient Information Sheet. The latter should have following components as may be applicable :

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations, if any, to be performed
5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
6. Benefits to participant, community or medical profession as may be applicable
7. Policy on compensation
8. Availability of medical treatment for such injuries or risk management
9. Alternative treatments if available
10. Steps taken for ensuring confidentiality
11. No loss of benefits on withdrawal
12. Benefit sharing in the event of commercialization
13. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury
14. Contact details of Chairman of the IEC for appeal against violation of rights
15. Voluntary participation
16. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

A copy of the participant/patient information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits.

Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained.

When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of EC is required for such procedures. For drug trials, if the volunteer can give only thumb impression then another thumb

impression by the relative or legal custodian cannot be accepted and an unrelated witness to the project should then sign.

Fresh or re-consent is taken in following conditions :

1. Availability of new information which would necessitate deviation of protocol.
2. When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected then procedures to address it should be spelt out in the informed consent form.
3. When long term follow-up or study extension is planned later.
4. When there is change in treatment modality, procedures, site visits.
5. Before publication if there is possibility of disclosure of identity through data presentation or photographs (which should be camouflaged adequately).

Waiver of consent

Voluntary informed consent is always a requirement for every research proposal. However, this can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations elaborated in the previous Chapter. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then IECs may waive off the requirement for informed consent in following instances:

1. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective, *eg.*, study on disease burden of HIV/AIDS.
2. Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
3. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries *etc.*
4. In emergency situations when no surrogate consent can be taken.

2. Obligations of investigators regarding informed consent : The investigator has the duty to

1. Communicate to prospective participants all the information necessary for informed consent. Any restriction on participant's right to ask any questions related to the study will undermine the validity of informed consent;
2. Exclude the possibility of unjustified deception, undue influence and intimidation. Although deception is not permissible, if sometimes such information would jeopardize the validity of research it can be withheld till the completion of the project, for instance, study on abortion practices;
3. Seek consent only after the prospective participant is adequately informed. The investigator should not give any unjustifiable assurances to prospective participant, which may influence the her/his decision to participate;
4. Obtain from each prospective participant a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in

case the participant is not competent to do so, a legal guardian or other duly authorised representative;

5. Take verbal consent when the participant refuses to sign or give thumb impression or cannot do so. This can then be documented through audio or video means;
6. Take surrogate consent from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody;
7. Renew or take fresh informed consent of each participant under circumstances described earlier in this chapter;
8. If participant loses consciousness or competence to consent during the research period as in alzheimer or psychiatric conditions, surrogate consent may be taken from the authorized person or legal custodian.

The investigator must assure prospective participants that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

3. Essential information for prospective research participants : Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language she or he is able to understand which should not only be scientifically accurate but should also be sensitive/ adaptive to their social and cultural context:

- I. The aims and methods of the research;
- II. The expected duration of the participation;
- III. The benefits that might reasonably be expected as an outcome of research to the participant or community or to others;
- IV. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which s/he is being subjected;
- V. Any foreseeable risk or discomfort to the participant resulting from participation in the study;
- VI. Right to prevent use of her/ his biological sample (dna, cell-line, etc.) At any time during the conduct of the research;
- VII. The extent to which confidentiality of records could be maintained ie., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;
- VIII. Responsibility of investigators;
- IX. Free treatment for research related injury by the investigator and/ institution and sponsor(s);
- X. Compensation of participants for disability or death resulting from such injury;
- XI. Insurance coverage if any, for research related or other areas;
- XII. Freedom of individual / family to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to;
- XIII. The identity of the research teams and contact persons with address and phone numbers;
- XIV. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;
- XV. Risk of discovery of biologically sensitive information and provision to safeguard confidentiality;

XVI. Publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social and marginalized groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

2. COMPENSATION FOR PARTICIPATION

Participants may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. When this is reasonable then it cannot be termed as benefit. During the period of research if the participant requires treatment for complaints other than the one being studied necessary **free ancillary care** or appropriate referrals may be provided. However, payments should not be so large or the medical services so extensive as to make prospective participants consent readily to enroll in research against their better judgment, which would then be treated as undue inducement. All payments, reimbursement and medical services to be provided to research participants should be approved by the IEC.

Care should be taken :

- i. When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
- ii. When a participant is withdrawn from research for medical reasons related to the study the participant should get the benefit for full participation;
- iii. When a participant withdraws for any other reasons s/he should be paid an amount proportionate to the amount of participation.

3. CONFLICT OF INTEREST

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI).

Academic institutions conducting research in alliance with industries/ commercial companies require a strong review to probe possible conflicts of interest between scientific responsibilities of researchers and business interests. g(ownership or part-ownership of a company developing a new product). In cases where the review board/ committee determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants, the board/ committee should advise accordingly. Significant financial interest means anything of monetary value that would reasonably appear to be a significant consequence of such research including salary or other payments for services like consulting fees or honorarium per participant; equity interests in stocks, stock options or other ownership interests; and intellectual property rights from patents, copyrights and royalties from such rights. The investigators should declare such conflicts of interest in the application submitted to IEC for review. Institutions and IECs need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. The IEC can determine the conditions for management of such conflicts in its SOP manual. Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research. Those who have also to be informed of the secondary interest in financial terms should include the institution, IEC, audience when presenting papers and should be mentioned when publishing in popular media or scientific journals.

Undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes. Undue compensation would include assistance to related person(s) for transport of body for cremation or burial, provision for insurance for unrelated conditions, free transportation to and fro for examination not included in the routine, free trip to town if the participants are from rural areas, free hot meals, freedom for prisoners, free medication which is generally not available, academic credits and disproportionate compensation to researcher / team/ institution. However, in remote and inaccessible areas some of the features mentioned above may be a necessity and culture specific. Therefore, the IEC should examine this on a case-by-case basis, as some of these elements may be justifiable for collecting vital data for national use or necessary to find if some interventions may significantly have direct impact on health policies.

4. SELECTION OF SPECIAL GROUPS AS RESEARCH PARTICIPANTS

i. *Pregnant or nursing women* : Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical

trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

- a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.
- b. Research related to termination of pregnancy : Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.
- c. Research related to pre-natal diagnostic techniques : In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

ii. *Children* : Before undertaking trial in children the investigator must ensure that -

- a. Children will not be involved in research that could be carried out equally well with adults;
- b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the

phase iii clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;

- c. A parent or legal guardian of each child has given proxy consent;
- d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
- e. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
- f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
- g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
- h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
- i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

iii. Vulnerable groups : Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- a. Research on genetics should not lead to **racial inequalities**;
- b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;
- c. Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;
- d. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. Who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.

5. CONFIDENTIALITY FOR RESEARCH PARTICIPANTS

Safeguarding confidentiality - The investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual participants.

Data of individual participants can be disclosed under the following circumstances :

- a. Only in a court of law under the orders of the presiding judge or
- b. There is threat to a person's life or
- c. In cases of severe adverse reaction may be required to communicate to drug registration authority or
- d. If there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority.

Therefore, the limitations in maintaining the confidentiality of data should be anticipated and assessed and communicated to appropriate individuals or authorities as the case may be.

6. COMPENSATION FOR ACCIDENTAL INJURY

Research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.

In case of death, their dependents are entitled to material compensation.

Obligation of the sponsor to pay :- The sponsor whether a pharmaceutical company, a government, or an institution, should agree, before the research begins, in the *a priori* agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.

An Arbitration committee or appellate authority could be set up by the institution to decide on the issue of compensation on a case-by-case basis for larger trials where such a step is feasible. Alternately an institution can also establish such a committee to oversee such claims, which would be common for projects being undertaken by it.

Compensation for ancillary care for unrelated illness as free treatment or appropriate referrals may also be included in the *a priori* agreement with the sponsors whenever possible.

7. MONITORING AND REPORTING ADVERSE REACTIONS OR EVENTS

Any adverse event or adverse drug reaction (AE/ ADR) can be expected and unexpected. These should be specified in the concerned SOP. Based on medical criteria they can be mild, moderate or severe/ serious and causality relationship should be examined. An AE or unexpected ADR requires expedited review by the ethics committee. Unexpected AE/ ADRs and all SAE (serious adverse event) should be reported to the sponsor by the investigator within 24 hours and to the ethics committee that accorded approval to the study protocol within seven days. In the event of death the EC should also be informed within 24 hours. Any unexpected SAE as defined in the Indian GCP (Good Clinical Practice) Guidelines occurring during a clinical trial should be communicated promptly within 14 calendar days by the Sponsor to the Licensing Authority and to the Investigator(s) of other trial sites participating in the study. The reporting of the SAE to the regulatory authority immediately is to enable it to stop the clinical trials of unapproved drugs or withdraw from market approved drugs based on report of Phase IV studies. All other serious unexpected reactions (ADRs) that are not fatal or life threatening must be filed as soon as possible but not later than 14 calendar days. At the end of the trial, all adverse events whether related to trial or not are to be listed, evaluated and discussed in detail in the final report.

The medical management of the adverse event is the responsibility of the investigator, and the protocol for adverse event management with allocation of responsibilities must be pre-defined in the protocol and submitted to the Ethics Committee. There must be a financial plan (including, if necessary, insurance) to manage adverse events and compensation for trial related injury. The Ethics Committee reviewing the protocol must review these aspects as well before giving approval.

8. CLINICAL TRIALS WITH SURGICAL PROCEDURES / MEDICAL DEVICES

Medical and health care technology has undergone rapid transformation in the past two decades. Of late, a series of technological inventions have revolutionized the preventive, diagnostic, rehabilitative, therapeutic (life-supporting or life sustaining devices) capabilities of medical sciences and biomedical technology has made considerable progress in the conceptualisation and designing of bio-equipments.

Several biomedical devices and critical care equipment have been imported and successfully deployed in diagnostic and therapeutic services in the country. Similarly, various academic and research organizations as well as private entrepreneurs are taking active interest in the development and manufacture of medical devices. Several important devices such as cardiac valve and spin offs from defence research laboratories like Kalam-Raju Stent, cardiac catheters, eye lasers and external cardiac pacemaker have been successfully developed and many more are in various stages of development.

However, only through good manufacturing practices (GMP) can the end products reach the stage of large scale utilisation by society. Most of these products are only evaluated by Central Excise testing for taxation purposes, which discourages entrepreneurs to venture in this area with quality products especially when they do not come under the strict purview of the existing regulatory bodies like ISI, BSI and Drugs Controller General. This is evidenced by the very low number of patents or propriety medical equipments manufactured and produced in the country.

9. DIAGNOSTIC AGENTS - USE OF RADIO - ACTIVE MATERIALS AND XRAYS

In human beings, for investigation and treatment, different radiations - X-ray, gamma rays and beta rays -, radiopaque contrast agents and radioactive materials are used. The relative risks and benefits of research proposal utilising radioactive materials or X-rays should be evaluated. Radiation limits for the use of such materials and X-rays should be in accordance with the limits set forth by the regulatory authority for such materials (BARC – Bhabha Atomic Research Centre, Mumbai).

Special Concerns

- a. Informed consent should be obtained before any diagnostic procedures.
- b. Information to be gained should be gathered using methods that do not expose participants to more radiation than exposed normally.
- c. In the event of death of a participant with radiological implant, due precaution as per radiation guidelines may be taken not to expose the relatives or the close co-habitants to radiation till safe.
- d. Research should be performed on patients undergoing the procedures for diagnostic or therapeutic purposes.
- e. Safety measures should be taken to protect research participants and others who may be exposed to radiation.
- f. The protocol should make adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo.
- g. Information must be given to participant about possible genetic damage to offspring.
- h. Non-radioactive diagnostic agents are considered as drugs and the same guidelines should be followed when using them.
- i. Ultrasound should be substituted wherever feasible.

10. CLINICAL EVALUATION OF TRADITIONAL AYURVEDA, SIDDHA, UNANI (ASU) REMEDIES AND MEDICINAL PLANTS

Self medication and greater orientation towards preventive health care, the growing desire of the aging population to stay young and healthy, and the increasing healthcare costs of therapy provided by Modern Medicine have led to more usage of traditional remedies. However, the improved research technology tools and growth deciders like new Biotechnology developments for producing the evidence, together with media publicity have catapulted traditional knowledge to the status of a hidden treasure worth exploring. Nevertheless, subjecting traditional remedies to the same rigours that synthetic drugs undergo to establish their safety and efficacy is a difficult proposition, as most of them are complex combinations leading to difficulty in assessment of their activity and risk/benefit ratio. This involves four sets of issues - chemical-manufacturing-control (CMC) issues, non-clinical issues, clinical issues, and ethical issues.

11. EPIDEMIOLOGICAL STUDIES

Epidemiological studies are generally considered in two categories – observational and experimental. Designs of these studies are based on cross-sectional, case-control or cohort approaches. Epidemiological studies cover research, programme evaluation and surveillance. Ethics in epidemiological studies is multidimensional covering clinical medicine, public health and the social milieu. The code of ethics is much better understood for clinical research, where the interaction between a patient and a clinical researcher is of supreme importance. In epidemiological research the researcher is dealing with a group of individuals and the questions faced by an epidemiologist are more of a professional nature. These questions would pertain to interactions with individual participants, sources of funding or employer, fellow epidemiologist and the society at large. Need for a code of ethics for epidemiologists is being recognized globally and the issues for such a code in the context of epidemiological research in India deserve attention.

Epidemiological research differs from clinical research in the context of the large number of study participants and generally a long time frame. If some mistakes or aberrations get detected during the course of conduct of such studies, repeating the whole exercise will be expensive, time consuming and may not even be feasible.

Hence utmost care needs to be taken for various aspects - technical, practical and ethical.

DEFINITIONS

Observational Epidemiology : In observational studies predefined parameters in a defined population group over a specified period and frequency are recorded for studying exposure to risks affecting health. These may be of the following types :

a. Cross Sectional Studies (Surveys) : This is primarily population based and involves selecting an entire population or random samples of the representative population based on census data and then using questionnaires to understand the prevalence of various diseases. Its aim is to assess aspects of the health of a population or to test hypotheses about possible cause of disease or suspected risk factors. The study participants are directly contacted only once in the defined period for which informed consent is required to be taken.

b. Case Control Studies: This usually compares the past history of exposure to risks among patients who have a specified condition/disease (cases) with the past history of exposure to this among persons who resemble the cases in such respects as age, sex socioeconomic status, geographic location, but who do not have the disease (controls). Case control studies can be done by following up available records, usually records in a hospital, but in the context of a country like ours it may require direct contact between research workers and study participants and informed consent to participate in the study is necessary. However, if it entails only a review of medical records, informed consent may not be required and indeed may very often not be feasible. But for such waiver of consent approval from IEC would be necessary.

c. Cohort Studies: These are longitudinal or prospective studies of a group of individuals with differing exposure levels to suspected risk factors. They are observed over a long period usually several years. The rate of occurrence of the condition of interest is measured and compared in relation to identified risk factors. It requires a study of large number of participants for a long time and involves asking questions, checking of records, routine medical examination and sometimes laboratory investigations. Individuals are being followed up as the cohort and it is essential to identify precisely every individual to be studied.

Experimental Epidemiology : In experimental epidemiology the investigators alter one or more parameters under controlled conditions to study the effects of the intervention on health. These are usually randomised controlled trials done to test a preventive or therapeutic regimen or the efficacy of a diagnostic procedure. Although these are strictly speaking epidemiological studies they come under the purview of clinical evaluation of drugs /devices / products / vaccines etc. The possibility of use of placebo as one of the arm of the trial should be explained and informed consent taken in such studies.

SPECIFIC PRINCIPLES

- 1. Informed Consent :** When individuals are to be included as participants of any epidemiological studies, the purpose and general objectives of the study has to be explained to them keeping in mind their level of understanding. It needs to be ensured that privacy will be maintained. In the context of developing countries, obtaining informed consent has been considered many times as difficult/ impractical / not meeting the purpose on various grounds such as incompetence to comprehend the meaning or relevance of the consent and culturally being dependent on the decision of the head of the family or village/ community head. However, **there is no alternative to obtaining individual's informed consent** but what should be the content of the informed consent is also a crucial issue. In spite of obtaining informed individual consent, it is quite likely that the participants/ patients may not be fully aware of their rights. In this context, the role of investigator is crucial and s/he should remain vigilant and conscious of her/ his obligations towards the participants/ patients, all through the course of the studies.
- 2.** In most epidemiological research it would be necessary to have the **consent of the community**, which can be done through the Village Leaders, the Panchayat head, the tribal leaders *etc.* who are considered to be gate keepers of the society/ community
- 3.** In obtaining the consent of individuals or communities it is important to keep in mind that working through peer groups or through Panchayat *etc.* may mean that the individuals or community would feel reluctant to disagree and refuse to give consent because of **societal pressures**. This is something that has **to be carefully avoided**.

4. Particularly in a country like India, with the level of poverty that is prevalent it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. **Such inducements are not permissible.** However, it is necessary to provide for adequate compensation for loss of wages and travel / other expenses incurred for participating in the study.
5. **All risks involved** including the risk of loss of privacy must be explained to the participants in an epidemiological study. Steps should be taken to maintain utmost privacy which should be informed to the community.
6. **Maintaining confidentiality** of epidemiological data is absolutely essential. A particular concern is the fact that some population based data may also have implications on issues like national security and these need to be carefully evaluated at the beginning.
7. All attempts should be made to **minimise harm** to the individuals and society at large. Special consideration for the cultural characteristics of the communities that are being studied is essential to prevent any disturbance to cultural sensitivities because of the investigation.
8. The design of the study should ensure that the **benefits of the study are maximised** for the individuals and communities taking part in the study. This means that at the onset itself the investigators should design the way in which the results of the study are going to be communicated and also decide whether individuals identified at particular risk during the course of the studies would be informed. It may also be necessary in some instances to inform the concerned family members about the results, for instance, as in AIDS, STD etc. It may not always be possible to communicate study results to individuals but research findings and advice should be publicized by appropriate available means. It is also important that the beneficial results of epidemiological studies are fed into the health system and necessary training modules should be developed as part of the epidemiological project.
9. In all situations where there is likely to be **conflicts of interest** it must be ensured that the interest of the individuals involved in the study are protected at all cost, for *eg.*, studies on outbreaks, epidemics, disasters and calamities, and epidemiological studies undertaken by providers of relief and rehabilitation.
10. Scientific objectivity should be maintained with honesty and impartiality, both in the design and conduct of the study and in presenting and interpreting findings. Selective withholding of data and similar practices are unethical.
11. **Benefits :** When epidemiological studies (like those on mortality and morbidity as a result of exposure to an agent) lead to long associations with the community, the results if released in timely manner could give improved health care facilities or educate the community to reduce the impact of adverse environment on health and tackle the problem at their end in time.
12. **Ethical Review Procedures:** In all Ethical Committees at least one or two individuals with an understanding of the principles of epidemiological ethics have to be included. These Committees should be independent and comprise of epidemiologists, clinicians, statisticians, social scientists, philosophers, legal experts and representatives from community/ voluntary groups who should be aware of local, social and cultural norms, as this is the most important social control mechanism.
13. **Distinction between research and programme evaluation:** It is difficult to make a distinction between epidemiological research and programme evaluation.

Whenever a programme evaluation and surveillance is launched, the monitoring and evaluating mechanisms should clearly be planned and cleared by IEC before initiation as is done in all epidemiological studies.

It is not always possible to know what will happen to the participants as unexpected results or undesirable events can sometimes occur. Very often the benefits and risks of the research pertain not only to the individual participants, but also the community from which they are drawn. Therefore, the participation of local community representatives in planning, conducting and monitoring research is important to avert circumstances which may be detrimental to the participants' welfare. This also helps in improving the vision of the researcher regarding the objectives and the design of study. The inclusion of a community representative to act on behalf of all participants involved in a research study Communities should be informed of the research, possible outcomes (positive and negative), and the results of the research. Research findings belong to participants and their communities as well as the researchers and the research community. Community representatives and researchers can work together to make sure that research is conducted in the most appropriate way and the benefits if any, could be shared in a reasonable or workable manner.