Institutional Review Board/ Independent Ethics Committee

INTRODUCTION

- Experimentation on human being is subject to ethical standards that promote respect for all and protect their health and rights.

Research requiring ethical review:

- Research involving living human subjects and use of their medical records.
- Research involving human remains, cadavers, biological fluids, tissues, embryos, fetuses and etc.

INTRODUCTION

- The “Institutional Review Board” (IRB) is a local administrative body established to protect the rights, safety, and well-being of human research subjects recruited to participate in a clinical research.
- The IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.
- The IRB provides assurances to research subjects that every reasonable attempt has been made to protect their rights and safety as subjects.

CONSTITUTION OF IRB

- The IRB should consist at least SEVEN members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. viz.

1. Chairperson - Appointed (who is from outside the institution)
2. 1-2 basic medical scientists
3. 1-2 clinicians from various institutes
4. One legal expert or retired judge
5. One social scientist
6. One philosopher or ethicist
7. One lay person from community
8. Member secretary - Appointed

QUORUM OF IRB

- For reviewing and making decision on each protocol the quorum of IRB should be atleast FIVE members with the following representations:

1. Basic medical scientists (preferably one pharmacologist)
2. Clinicians
3. Legal expert
4. Social scientist / Representative of non-governmental voluntary agency / Philosopher / Ethicist / Theologian or a similar person
5. Lay person from the community

QUORUM OF IRB

- In any case, the IRB must include

a) at least one member whose primary area of interest / specialization is nonscientific

b) at least one member who is independent of the institution / trial site

- Besides, there should be appropriate gender representation on the IRB.
- If required, Subject experts may be invited to offer their views.
- Further, based on the requirement of research area, e.g. AIDS, genetic disorders etc. specific patient groups may also be represented in the IRB.

FUNCTIONS AND OPERATIONS OF IRB

- Only those IRB members who are independent of the clinical trial and the Sponsor of the trial should vote / provide opinion in matters related to the study.
- Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.
- The IRB should perform its functions according to written standard operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

FUNCTIONS AND OPERATIONS OF IRB

- The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB or in the vote/opinion of the IRB.
- The IRB should establish, document in writing, and follow its procedures, which should include
- Determining its composition (names and qualifications of the members)
- Scheduling, notifying its members of, and conducting its meetings
- Conducting initial and continuing review of trials
- Determining the frequency of continuing review, as appropriate

FUNCTIONS AND OPERATIONS OF IRB

- Specifying that no subject should be admitted to a trial before the IRB issues its written approval / favorable opinion of the trial.
- Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB approval / favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial.

FUNCTIONS AND OPERATIONS OF IRB

- Specifying that the investigator should promptly report to the IRB.
- Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects.
- Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial.
- All adverse drug reactions (ADRs) that are both serious and unexpected.
- New information that may affect adversely the safety of the subjects or the conduct of the trial

FUNCTIONS AND OPERATIONS OF IRB

- Ensuring that the IRB promptly notify in writing the investigator/institution concerning.
- Its trial-related decisions/opinions .
- The reasons for its decisions/opinions.
- Procedures for appeal of its decisions/opinions

RESPONSIBILITIES OF IRB

- An IRB should safeguard the rights, safety, and well- being of all trial subjects.
- The IRB should obtain the following documents.
- Trial protocol(s)/amendment(s) ▫Written informed consent form(s).
- Subject recruitment procedures (e.g.: Advertise).
- Written information to be provided to subjects.
- Investigator's Brochure (IB).
- Available safety information.
- Information about payments and compensation.
- Investigator's current curriculum vitae.
- Any other may need to fulfill its responsibilities.

RESPONSIBILITIES OF IRB

- The IRB should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following.
- Approval / favourable opinion.
- modifications required prior to its approval / favourable opinion;
- disapproval / negative opinion
- Termination / suspension of any prior approval / favourable opinion
- The IRB should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and / or by any other relevant documentation the IRB requests.

RESPONSIBILITIES OF IRB

- The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.
- The IRB may request more information than is given to study subjects when, in the judgement of the IRB the additional information would add meaning to the protection of the rights, safety and/or well-being of the subjects.
- The IRB should review both the amount and method of payment to subjects to assure neither compulsion nor undue influence on the trial subjects.

RESPONSIBILITIES OF IRB

- Payments to a subject should be prorated (day basis) and not wholly contingent on completion of the trial by the subject.
- The IRB should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects

INFORMED CONSENT FORM

- A major component of GCP is the method by which the researchers will obtain voluntary and informed consent from subjects
- Informed consent is a process, not just a form
- Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject
- The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand

INFORMED CONSENT FORM

- In seeking informed consent the following information should be provided to the subject
- Statement that the study involves research and explanation of the purpose of the research
- Expected duration of the Subject's participation
- Description of the procedures to be followed, including all invasive procedures and
- Description of any reasonably foreseeable risks or discomforts to the Subject
- Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

INFORMED CONSENT FORM

- Disclosure of specific appropriate alternative procedures or therapies available to the Subject
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
- Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
- Compensation and/or treatment(s) available to the Subject in the event of a trial related injury

INFORMED CONSENT FORM

- An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
- The anticipated prorated payment, if any, to the Subject for participating in the trial
- Subject's responsibilities on participation in the trial
- Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled

INFORMED CONSENT FORM

- Any other pertinent information which may be required, viz.

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the investigator without the subject's consent

b. Additional costs to the subject that may result from participation in the study

c. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject

d. Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided

e. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

f. Approximate number of Subjects enrolled in the study

FORMAT OF INFORMED CONSENT FORM

Informed Consent Form To Participate In A Clinical Trial

Study Title:

Study Number:

Subject's Initials: _____

Subject's Name:_____

Date of Birth / Age: _____

FORMAT OF INFORMED CONSENT FORM

Please initial in boxes:

1. I am above 18 years old [ ]
2. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions [ ]
3. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected [ ]
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

FORMAT OF INFORMED CONSENT FORM

Please initial in boxes:

.....

.....

5.I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Date:__/__/__ Signatory's Name: _____ Signature of the Investigator:_____ Date: __/__/__

FORMAT OF INFORMED CONSENT FORM

Study Investigator's Name:_____

Signature of the Witness_____

Date:__ /__ /__

Name of the Witness:_____