Institutional Ethics Committee
Sanjay Gandhi Postgraduate Institute of Medical Sciences
(IEC, SGPGI)

Appendices

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AP1/V3

Policy on the Recruitment of Research Participants

Specific recruitment guidelines

1. In addition to its review for scientific merit and protection of subjects from unnecessary research risks, the IEC will evaluate all protocols for subject recruitment especially with respect to women with childbearing potential, children and normal volunteers as controls. Exclusion of women of child bearing age or children will be recommended or approved when inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.
2. SGPGI patients - Patients may be identified as potential research subjects through direct contact of the PI with the patients, collaboration with physicians of other medical specialties, contact with individual attending physicians, posted written notices, radio announcements, or other IEC approved methods.

a. **Inpatients** - May be recruited by the investigator or other member of the research team only after consultation with the patient's attending physician.

b. **Outpatients**

1. For minimal risk research which does not bear directly upon a specific continuing therapeutic relationship between the individual and a SGPGI physician, outpatients may be recruited without prior notification of their personal physicians. However, when possible, subject's personal physician should be notified of the study and informed that the patient has been entered into a clinical study.

c. Community studies

Epidemiology is defined as the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to control health problems. Epidemiological studies are of primary importance in a large developing country like ours where the natural history, incidence, prevalence and impact on morbidity and mortality of a variety of diseases are not known. Such studies are on large scale and assist in improving the public health, which includes both patients and healthy people and communities.

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. 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.

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.

A community can be defined as a group of people sharing the same location, beliefs, culture, ideals, goals, age, gender, profession, lifestyle, common interests, geographical locations or settings or disease. When research participants are drawn from a specific community, members of that community can be involved to discuss any concerns it may have regarding the research. In different ways such a dialogue can be facilitated.

If an ethics committee does not have a member from the community, it may ask a local community representative to be the voice for all participants. On the other hand, community representatives can formally join together to form a group termed as Community Advisory Board, Community Working Group, or Community

Advisory Group, which takes part in the research at all stages of the study. In international studies, particularly on issues involving communities, representation from this body ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits is provided through research that is designed and implemented in the best interests of science and community.

Community representation should be involved before, during and after the study.

Before the study is initiated the community is informed to see if it agrees that the research addresses a need or problem relevant to that community and to confirm that the design is culture specific and brings some benefits to research participants or the community. Since some risk may be associated the community representation is needed to assist in developing appropriate ways to protect the participants. During the study, the association with community representatives continues to educate others about the research and to alert the researcher to ethical issues related to the research. After the study is completed, community representatives can help in making the results known to the entire community. However, application of research findings may take a long time, which the community representatives should be made to understand. The benefits may be participants' and community's access to intervention. Whose responsibility and conditions under which this would be done, duration of availability of intervention, methods of improving the quality of health care in the community and any expected desirable behavioral change in the community should be clearly explained to community by the Ethics Committee or community representatives.

AP2/V3

Policy on Research Costs to Participants

If a research participant has to bear any costs, all potential participants must be fully informed of the nature and estimated extent of these costs when obtaining consent. Examples of additional research costs include:

1. Prolongation of treatment or hospitalization.
2. Extra diagnostic tests necessary for the research.
3. Extra clinical or laboratory assessments to evaluate research treatment outcome.
4. A research treatment (whether randomly assigned or not) which may be costlier than a standard treatment.
5. Other substantial costs associated with extra visits to SGPGI.

AP3/V3

Guidelines on Compensation for Research Participants

1. http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (pg 8-9)
2. www.cdsco.nic.in**Formula to Determine the quantum of compensation in the cases of Clinical Trial related serious Adverse Events(SAEs) of Injury other than Deaths Occurring During Clinical Trials**

We will also follow guideline issued by DCGI time to time (Gazette notification).

AP4/V2

Policy on the Use of Third Party/Surrogate Consent in Research at SGPGI

Applicability

When a SGPGI investigator proposes to conduct a research, project utilizing adult subjects who by virtue of age, physical impairment, mental impairment, language barrier or any other reason may not be able to personally execute legally effective informed consent, the IEC shall review the project on the basis of "risk" and "benefit" and shall determine that each project be assigned to one of the categories below. This policy does not mean to imply that the requirement for written documentation of consent is waived. Rather, it applies to those studies in which third party/surrogate consent is obtained from a legally authorized representative.

Investigators must complete and submit an IEC Form for review and approval of inclusion of subjects who are decisional impaired.

Category I - Risks to subjects are minimal, direct benefits may or will accrue to subjects.

Category II - Risks to subjects are minimal, direct benefits will not, or are unlikely, to accrue to subjects but potential societal benefits are inherent in research.

Category III - Risks to subjects are greater than minimal, direct benefits may or may not accrue to subjects.

Category IV - Risks to subjects are greater than minimal, direct benefits will not, or are unlikely, to accrue to subjects but potential societal benefits are inherent in the research.

IEC recommendations to the administration

When categorization has been accomplished, the IEC will recommend to the SGPGI Administration to consider implementation or non-implementation of the project based upon the level of benefit to be gained by the individual or society from this project as compared to the level of risk involved.

IEC will recommend normally Category I projects to be initiated.

IEC will not recommend normally initiation of any Category IV projects.

IEC recommendation on Category II and III projects will depend on case to case assessment of risk/benefit ratio to subject and community.

AP5/V2

Guidelines on Blood Withdrawal for Research Purposes

Applicability

For many studies where the only research intervention is the collection of blood for analysis, the IEC categorizes the following procedures for obtaining blood from children and adults as having minimal risk:

A. General Requirements

1. There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.

2. Participants in whom blood is already being drawn for clinical purposes, there are no other health reasons to preclude additional blood collection provided the amount is limited to as mentioned in B and C.

3. In subjects from whom blood is not already being drawn for clinical purposes, the withdrawal method is by cutaneous pricks (e.g., heel or finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures should not exceed two per week except in pharmacokinetic study.

4. The volume of blood drawn from lactating or known pregnant subjects does not exceed 20 ml per week.

5. All blood withdrawals and collections should be carried out by experienced professional or technical personnel.

B. Additional Requirements for Adults (Subjects over 18 years of age)

1. If less than 50 ml is being collected, there are no additional restrictions with regard to hemoglobin or hematocrit.
2. If a volume greater than 50 but less than 200 ml is being collected for "no-benefit" studies, hemoglobin levels should be >11.0 g/dl for males and >9.5 g/dl for females with MCVs >85 fl (These restrictions would not apply if iron deficiency anemia or other forms of anemia were critical for inclusion in the study).
3. The cumulative volume withdrawn or collected may not exceed 450 ml per twelve-week period (this maximum includes blood being drawn for clinical purposes) from patients 18 years of age or older in good health and not pregnant.

C. Additional Requirements for Children (Subjects under 18 years of age

1. No more than three (3) skin punctures are to be made in any single attempt to draw blood, and the frequency of punctures does not exceed twice per week.
2. The volume of blood withdrawn, including blood for clinical purposes, does not exceed the limit of 50 ml or 3 ml/kg in an eight-week period and collection may not occur more frequently than 2 times per week.
3. The cumulative volume of clinical and research blood withdrawn per eight-week period does not exceed six per cent (6.0%) of the child's total blood volume.
4. In patients from whom blood is already being drawn for clinical purposes and when the research is directly related to the child's condition, there is no maximum number of extra volume specimens which can be collected as long as the preceding requirements are met.
5. In subjects from whom blood is not already being drawn for clinical purposes, the maximum number of allowable separate specimens (again, within the limits of the preceding restrictions) depends upon the child's age and whether the research is directly related to the child's condition.

D. **Cord Blood**

Cord blood from newborns can be used without restrictions when blood is extracted from the placental side of the cord, after it has been clamped and severed.

AP6/V3

Guidelines for obtaining Informed consent [Participant Information Document and (PID) and Consent Form (CF)]

Available at http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (Page 50-68)

AP7/V3

Examples of PID (Hindi and English in Non-interventional studies)

Available at www.sgpgi.ac.in

AP8/V2

Health Record Research

The following is the IEC policy concerning research involving the study of medical records or other forms of health information.

Research projects may involve the study of Patient case files with the stipulations described below. Such studies raise issues of confidentiality that must be carefully addressed by the investigator and the official custodian of the records. If it is anticipated that if an individual's records or specimens are likely be used for research purposes, the potential subject should be informed of the potential use of such materials upon entry into the institution or program in which the materials will be developed or collected and be given an opportunity to either provide or refuse consent to such research. Patient case files may be used or disclosed for research purposes if it has been de-identified and linkage back to a specific patient would not be possible.

To use or disclose identifiable Patient case files without authorization of the research participant, the investigator must accomplish one of the following:

1. Complete and submit an IEC Form to request waiver of the requirements for obtaining informed consent;
2. Provide written documentation that the use of disclosure of patient case files is solely used to design a research protocol or to assess feasibility of conducting a study, or;
3. Document that the use or disclosure is solely for research on the patient case files of decedents.

Investigators must maintain in their files a letter from the IEC identifying the date on which the waiver or alteration of the requirements to obtain informed consent was approved by the IEC, and a statement that the IEC has determined that the waiver or alteration satisfies the following criteria:

1. The use or disclosure of patient case files involves no more than minimal risk to the research participants;
2. The alteration or waiver will not adversely affect the privacy rights and welfare of the subjects;
3. The research cannot practicably be conducted without the alteration or waiver;
4. The research could not practicably be conducted without access to or the use of the patient case files;
5. The privacy risks to individuals whose case files is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonable be expected to result from the research;
6. There is an adequate plan to protect the identifiers from improper use and disclosure;
7. There is an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, and;
8. There are adequate written assurances that the Patient case files will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of Patient case files would be permitted by this policy.

The IEC letter should also contain a brief description of the Patient case files for which use or access has been determined by the IEC to be necessary, a statement that the waiver or alteration was approved by Expedited Review or at a convened meeting, and the letter should be signed by the IEC Chair or the Member Secretary.

Research use or disclosure of identifiable Patient case files with authorization of the research participant is permitted providing that use or disclosure is for only the Patient case files that were originally authorized. In order to use or disclose additional information, the investigator would either have to obtain consent or request a waiver of the requirements to obtain consent.

AP9/V2

Guidelines for Research Protocols which require Collection and Storage of Genetic Materials

For the purpose of these guidelines, "Genetic Materials" are defined as human tissue samples (blood, serum, tumor, etc.) on which genetic related research, such as biochemical studies of inherited human traits or identification of DNA mutations may be performed.

A. Previously acquired samples

i. Previously acquired genetic material may be used if identifiers are stripped irrevocably from samples.

ii. If identifiers are present, experiments not described in present protocols must be submitted for fresh IEC review.

B. Prospectively acquired samples

1. Anonymous samples (further identification made impossible)

i. Ownership of genetic material will generally remain with the institution. This must be stated in the consent form.

ii. The general scope of the investigations must be explained in the consent form, but new avenues of investigation in the future are permissible if this possibility is explained in the consent form and agreed upon by the participant.

iii. Whether the genetic material will be shared by other investigators should be explicit in the consent form.

iv. The consent form should make clear that no specific information relative to the individual donor will be forthcoming; however, information that accrues from the study that is valuable to society may be shared with the individual.

2. Identified samples

i. If genetic material is linked to the donor by specific identifiers, ownership of the material will generally remain with the institution. If a commercial use is anticipated for the genetic material, the individual must be notified. The general policy of ownership should be stated in the consent form using the following wording:

"I understand that additional or "leftover" (blood, serum, tumor, etc.) tissue may be used for future research which may result in financial gain for SGPGI and the researchers. I also understand that my donated tissue will be one of many that are used in the research and it will be virtually impossible to attribute findings to any one sample. I understand, however, that I am not otherwise waiving any of my legal rights by participating in this study."

ii. If identifiers are present, new experiments must be reviewed by the IEC and new consent obtained from the research participant regardless of the details of ownership.

iii. The investigator may include a provision in the consent form for new experiments not requiring new consent if identifiers are irrevocably removed from the samples. If the investigator anticipates future experiments without identifiers, this possibility should be present in the original consent form. The methods for removal of identifiers must be approved by the EC. Removal of identifiers must not be employed as a method of avoiding ownership issues.

iv. A satisfactory method for sharing or withholding information gained by the research must be in the research protocol and clearly indicated in the consent form.

v. Details for sharing or not sharing the genetic material with other investigators must be present in the protocol and clearly indicated in the consent form.

vi. The length of time the genetic material will be maintained must be indicated in the consent form.

C. Donation of genetic material as a requirement for participation in a research protocol.

i. Donation of genetic material may be required for participation in a protocol only if the presence of the genetic material is necessary to satisfy the central question of the research.

ii. The investigator will be required to make a clear case in the research protocol for the necessity of the genetic material, if donation of genetic material is mandatory.

iii. This policy applies to genetic material with or without identifiers.

AP10/V3

Guidelines for Submission and IEC review of Gene Therapy/Gene Transfer Protocols

Available at: http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (pg 122)

AP11/V3

Ethical Policies on the Human Genome, Genetic Research and services, Department of Biotechnology, Ministry of Science and Technology, Govt. of India, 2002

Available at: https://www.india.gov.in/ethical-policies-human-genome-genetic-research-and-services-department-biotechnology

AP12/V3

Recommended Terms for Use in Informed Consent Document

To facilitate understanding of informed consent document by the participant, it is recommended that the language used is at a reading level of a12-year-old. The following lay terms, definitions and suggestions are recommended to help investigators in this process.

For	**Use**
adjuvant	helpful; assisting; aiding
ambulate (-action –ory)	walk; able to walk; ability to walk
ameliorate	make smaller or less, reduce
analgesia	pain relief
anaphylactic reaction	a severe and sometimes dangerous reaction which may cause problems breathing, fainting, itching and skin rash
anorexia	lack of appetite
arrhythmia	abnormal heartbeat
aspiration	removal by using a sucking machine; fluid entering the lungs
asymptomatic	without symptoms; having no symptoms
barrier method	diaphragm and condom (with spermicide), cervical cap, or sponge
benign	not malignant; usually without serious consequences
bolus	an amount given all at once
bradycardia	slow heartbeat
carcinogenic	capable of causing cancer
cardiac	heart
cerebral	the brain; of the brain
CHD	coronary heart disease; heart disease
controlled trial	study in which the experimental treatment is compared to a standard treatment
conventional therapy	standard treatment
coronary	pertaining to the blood vessels that supply the heart
CT (CAT)	scan computerized series of x-rays
cutaneous	relating to the skin
DCGI	Drug Controller General of India
diastolic	the lower number in a blood pressure reading
disseminated	widely-spread, all through the body
distal	toward the end; away from the center of the body
diuretic	drug that causes an increase in urine secretion
double-blind	neither the subject nor physician knows what is being given
dysfunction	improper function
dysplasia	abnormal cells
echocardiogram	sound wave test of the heart
edema	fluid in the tissues; puffiness; swelling
emesis	vomiting
endoscopic	examination of the inside of the body with a lighted tube
epidural	outside the spinal cord
erythrocyte	red blood cell
fibrillation	irregular heartbeat
fibrous	like scar tissue
granulocyte	white blood cell
hematocrit	concentration of red blood cells
holter monitor	portable machine for recording heartbeats
hypoxia	low oxygen level in the blood
immunosuppressive	a drug or therapy that reduces the body's ability to fight infection; helps prevent rejection of a transplanted organ

infarct	death of tissue due to loss of blood flow
intubate	the placement of a tube into the airway
ischemia	decrease in oxygen in a tissue, usually because of decreased blood flow
laparotomy	a procedure where an incision is made in the abdominal wall to enable a physician to look at the organs
lumen	cavity of an organ; inside a blood vessel
lymphocyte	a type of white blood cell important for defense against infections
marrow suppression	decreased growth of the bone marrow
metastasis	spread of cancer cells from one part of the body to another
monoclonal antibody	very specific, purified antibody
morbidity	sickness/illness
MRI	pictures of the body created using magnetic rather than x-ray energy
murine	obtained from mice
myalgia	muscle aches
myocardial	infarction heart attack
nasogastric	tube a tube from the nose to the stomach
necrosis	death of tissue
neoplasia	a tumor that may be cancerous or non-cancerous
neural	brain or nerves
neutropenia	decrease in white blood cells
occult blood test	testing a stool sample for invisible amounts of blood
oncology	the study of tumors or cancer
pancytopenia	low number of blood cells
Percutaneous	through the skin
phlebitis	irritation or inflammation of a vein
placebo	inactive medication; dummy pill; sugar tablet; containing no medication
platelets	blood cells that help the blood clot normally
prenatal	before birth
prognosis	outlook, probably outcomes
prophylaxis	a drug given to prevent disease or infection
prosthesis	artificial body parts, such as arms, legs, hips
proximal	closer to the center of the body, away from the end
psychosis	major psychiatric problem
pulmonary	pertaining to the lungs
radiotherapy	treatment with radiation
randomly assigned	similar to the toss of a coin; assignment to a treatment group by chance
refractory	not responding to treatment
regimen	pattern of giving treatment
renal	kidney
resect	remove or cut out surgically
somnolence	sleepiness
staging	a determination of the extent of the disease
stenosis	narrowing of a duct, tube, or blood vessel
stratify	arrange in groups by age, sex, etc., for analysis
subcutaneous	under the skin
supine	lying on the back
syndrome	a condition with a certain set of symptoms
systolic	the top number in blood pressure
tachycardia	fast heart beat
taper	decrease; reduce
thrombosis	to get or have a blood clot in a blood vessel
titration	gradual alteration of a drug dose to get the desired effect

topical	applied to the skin
transdermal	through the skin
uremia	kidney failure
varices	enlarged veins
vasodilation	widening of the blood vessels
vasospasm	narrowing of blood vessels due to a spasm of the vessel walls
venipuncture	taking blood from the vein

AP13/V3

From Essential documents for the Conduct of a Clinical Trial Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, Directorate General of Health Services, New Delhi, 2001

Available at: http://www.cdsco.nic.in/html/GCP1.html; **Good Clinical Practice Guidelines**

AP14/V3

WMA Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Participants

Adopted by the18th WMA General Assembly, Helsinki, Finland, June1964 and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

8th WMA General Assembly, Somerset West, Republic of South Africa, October1996,
35th WMA General Assembly, Venice, Italy, October1983

41st WMA General Assembly, Hong Kong, September 1989

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002(Note of Clarification added)

5th WMA General Assembly, Tokyo, Japan, October 2004(Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

64th WMA General Assembly, Fortaleza, Brazil, October 2013

Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

AP15/V2

IND Application Exemption Checklist

This checklist is intended to be used by the investigator as a preliminary test of whether an IND application needs to be submitted to the DCGI for studies involving DCGI/RA-approved drugs.
If any question is answered "yes", an IND application must be submitted to the DCGI. If the answers to all questions are "no", then the study may meet the criteria for an exemption from an IND.

1. Name of drug
   Dosage
   Route
2. Does the study involve a different route of administration of the marketed drug than already approved?
   ( ) YES ( ) NO
3. Does the study involve the administration of different drug dosage levels that significantly increase risk or decrease the acceptability of risk to study subjects?
   ( ) YES ( ) NO
4. Does the study involve the administration of the drug to a different patient population for whom there may be increased risk or decreased acceptability of risk?
   ( ) YES ( ) NO
5. Does the study entail any other factor that significantly increases the risk or decreases the acceptability of risk to study subjects?
   ( ) YES ( ) NO
6. Are the results of the study intended to be reported to the DCGI/RA in support of any significant change in labeling or advertising for the drug (only for corporate sponsored studies)?
   ( ) YES ( ) NO

Principal Investigator's signature: _____ Date _____

AP16/V3

Clinical Trial Registry – India

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdsco.nic.in). Moreover, Editors of Biomedical Journals of India declared that only registered trials would be considered for publication.

Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trial lists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display.

Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

AP17/V3

National Guidelines for Stem Cell Research (ICMR, 2017).

Available at: www.dbtindia.nic.in/wp-content/uploads/National_Guidelines_StemCellResearch-2017.pdf; http://www.dbtindia.nic.in/guidelines/

AP18/V3

Guideline for Medical Device Related Studies

As per Medical Device Rules 2016 and 2017 (Available at: www.cdsco.nic.in/)

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to commence from 01.01.2018.