Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY – 605 502

Date:06.02.2018.

From
Dr.S.Rajini
Professor and Head,
Department of Community Medicine,
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research,
Puducherry

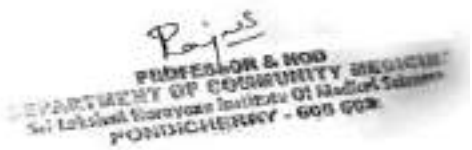
To
The Dean,
Sri Lakshmi Narayana Institute of Medical College
Bharath Institute of Higher Education and Research,
Puducherry

Sub: Permission to conduct value-added course: ETHICS AND RESEARCH

Respected Madam,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled: ETHICS AND RESEARCH from March – August 2018. We solicit your kind permission for the same.

Kind Regards



Head of Department

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY – 605 502

FOR THE USE OF DEANS OFFICE

Names of Committee members for evaluating the course:

The Dean:Dr.Sukumar

The HOD:Dr.Rajini

The Expert:Dr.Kannan Krishnamoorthy

The committee has discussed about the course and is approved.

PROFESSOR & HOD
DEPARTMENT OF COMMUNITY MEDICINE
Sri Lakshmi Narayana Institute of Medical Sciences
PONDICHERRY - 605 502.

Resource person

HOD
(Sign & Seal)

DEAN
DEAN

Dean
(seal & sign)

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST, PUDUCHERRY – 605 502

Circular

08.02.2018

Sub: Organising Value-added Course: ETHICS AND RESEARCH reg

With reference to the above mentioned subject, it is to bring to your notice that Sri Lakshmi Narayana Institute of Medical Sciences, **Bharath Institute of Higher Education and Research** is organizing VALUE ADDED COURSE on **"ETHICS AND RESEARCH"**.

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before March 1th,2018 . Applications received after the mentioned date shall not be entertained under any circumstances.

DEAN

VALUE ADDED COURSE

1. Name of the programme & Code

Ethics in research and PSM01

2. Duration & Period

30 hrs & March 2018 – August 2018

3. Information Brochure and Course Content of Value Added Courses

Enclosed as Annexure- I

4. List of students enrolled

Enclosed as Annexure- II

5. Assessment procedures:

Multiple choice questions- *Enclosed as Annexure- III*

6. Certificate model

Enclosed as Annexure- IV

7. No. of times offered during the same year: 1

8. Year of discontinuation:2019

9. Summary report of each program year-wise

Value Added Course- March 2018 – August 2018					
Sl. No	**Course Code**	**Course Name**	**Resource Persons**	**Target Students**	**Strength & Year**
1	PSM02	Ethics and research	Dr.Kannan.K Dr. Thiruselvakumar.D Dr.Kameshvell.C	III[rd] MBBS	1

10. Course Feed Back *Enclosed as Annexure- V*

PROFESSOR & HOD
DEPARTMENT OF COMMUNITY MEDICINE
Sri Lakshmi Narayana Institute of Medical Sciences
PONDICHERRY - 605 502

RESOURCE PERSON **COORDINATOR**

Annexure 1 -Course Proposal

Course Title: ETHICS AND RESEARCH

Course Objective:

1. Introduction to ETHICS AND RESEARCH
2. Ethical committee
3. Components
4. Project funding
5. Monitoring
6. Evaluation

Course Outcome:

Improvement in their knowledge on ETHICS AND RESEARCH

Course Audience: Pre-Final year students

Course Coordinator: Dr.S.Rajini

Course Faculties with Qualification and Designation:

1.Dr.K.Kanan, Assistant Professor

2.Dr.C.Kameshvell, Associate Professor

3.Dr.Thiruselvakumar,Associate Professor

Course Curriculum/Topics with schedule (Min of 30 hours)

s.no	Date	Topic	Time	Faculties	Hrs
1	08.03.18	Introduction	4-6 PM	Dr.K.Kannan	2hrs
2	15.03.18	Ethics- overview	4-6 PM	Dr.C.Kameshvell	2hrs
3	22.03.18	Issues with ethics	4-6 PM	Dr.K.Kannan	2hrs
4	05.04.18	Ethical committee	4-6 PM	Dr.Thiruselvakumar	2hrs
5	12.04.18	Functions of ethical committee	4-6 PM	Dr.C.Kameshvell	2hrs
6	19.04.18	Research- overview	4-6 PM	Dr.K.Kannan	2hrs
7	03.05.18	Research methods	4-6PM	Dr.Thiruselvakumar	2hrs
8	10.05.18	Importance of research	4-6 PM	Dr.C.Kameshvell	2hrs
9	17.05.18	Advantages of doing a research	4-6 PM	Dr.K.Kannan	2hrs
10	24.05.18	How to do a research study	4-6 PM	Dr.Thiruselvakumar	2hrs
11	07.06.18	Challenges in doing research	4-6 PM	Dr.C.Kameshvell	2hrs
12	14.06.18	Research in clinicals	4-6 PM	Dr.K.Kannan	2hrs
13	19.07.18	Publication	4-6 PM	Dr.Thiruselvakumar	2hrs
14	26.07.18	Exercises	4-6 PM	Dr.K.Kannan	2hrs
15	02.08.18	Summary	4-6 PM	Dr.C.Kameshvell	2hrs
		Total			30 hrs

REFERENCE BOOK

1.Aguinis H, Henle CA. Ethics in research. Handbook of research methods in industrial and organizational psychology. 2002;5:34-56.

Resnik DB. What is ethics in research & why is it important. Inideas 2015 Dec 1.

Ethics and research

Brouchure

INDIAN COUNCIL OF
MEDICAL RESEARCH
2018

HANDBOOK
ON
NATIONAL ETHICAL GUIDELINES
FOR BIOMEDICAL AND HEALTH RESEARCH
INVOLVING HUMAN PARTICIPANTS

INDIAN COUNCIL OF MEDICAL RESEARCH
2018

Edited & Coordinated by

Dr. Roli Mathur

Scientist 'E' & Head

ICMR Bioethics Unit

NCDIR, Bengaluru

Published by:

Director-General

Indian Council of Medical Research

New Delhi 110 029

www.icmr.nic.in

2018

Cover page:This is the image of the cover page of National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017. This handbook is prepared from this source document in 2018.

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एम.डी., डी.एम., एफआरसीपी (जी.), एफआरसीपी (ई.),
एफएसीसी, एफएएचए, एफएएसएस,
एफएमएस, एफएएससी
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एवं
महानिदेशक, आई सी एम आर

Prof. Balram Bhargava

Awarded Padma Shri by President of India
MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc

Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Research
&
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
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वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029 (भारत)

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029 (INDIA)

FOREWORD

ICMR released the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants in October 2017 and since then these guidelines have been widely disseminated to sensitize researchers as well as ethics committees about the updated ethical requirements. The guidelines have addressed contemporary and emerging ethical issues in great detail and must be followed by all institutions that are engaged in biomedical and health research in India.

In order to further provide a quick and easy reference of the ethical guidelines, ICMR has prepared a short user friendly handbook on National Ethical Guidelines. It has been prepared in very simple language and captures the essence of the source document "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017". The handbook will be very handy for use by students, clinicians and scientists and provides salient features of all 12 Sections covering the common ethical issues and concerns which come up in the conduct and review of research.

I hope this handbook will be found to be useful as a ready reference to safeguard the rights, safety and well-being of research participants as well as help to improve the quality of research outcomes. Gandhiji showed the path for protecting human dignity with truth, compassion and, sympathy and I am happy that this document released on the pious occasion of Gandhi Jayanti would help to enrich and uphold the ethical conduct of research and will be a tribute to his principles, science and mankind.

Balram Bhargava

(Balram Bhargava)

Tele.: 26588204, 26589620, Fax (Off.) : 91-11-26588662, E-mail: dg@icmr.org.in

INTRODUCTION

In October 2017, the Indian Council of Medical Research issued the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The purpose of these guidelines is to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research. These guidelines must be followed by all stakeholders including institutions, ethics committees (ECs), researchers and sponsors/ funding agencies.

This handbook provides a quick reference to all 12 sections of the ICMR National Ethical Guidelines, 2017. For complete details this source document may be referred to.

Scope

The guidelines are applicable to all biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material and data. The PURPOSE of such research should be:

i. DIRECTED towards enhancing knowledge about the human condition while maintaining sensitivity to the Indian cultural, social and natural environments.
ii. CONDUCTED under conditions such that no person or persons become mere means for the betterment of others and that human beings who are subjected to any biomedical and/or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency.
iii. SUBJECTED to a regime of EVALUATION at all stages, i.e., design, conduct and reporting of the results thereof.

STATEMENT OF GENERAL PRINCIPLES

1.1. Every research has some inherent probabilities of harm or risk and thus, protection of research participants and/or communities should be built into the design of the study.

1.2. While conducting biomedical and health research, the four basic principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice must guide research in order to protect the dignity, rights, safety and well-being of research participants.

1.3. ECs must ensure that the research is conducted in accordance with the basic principles.

1.4. The basic principles have been expanded into 12 general principles (Table 1), that are applicable to all biomedical and health research involving human participants or research using their biological material or data.

Table 1: General Principles

1. Principle of Essentiality	7. Principle of Professional Competence
2. Principle of Voluntariness	8. Principle of Maximization of Benefit
3. Principle of Non-exploitation	9. Principle of Institutional Arrangements
4. Principle of Social Responsibility	10. Principle of Transparency & Accountability
5. Principle of Ensuring Privacy & Confidentiality	11. Principle of Totality of Responsibility
6. Principle of Risk Minimization	12. Principle of Environmental Protection

GENERAL ETHICAL ISSUES

There are some general issues that must be kept in focus during the conduct of biomedical and health research involving human participants (Table 2).

Table 2: General Ethical Issues

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Selection of vulnerable and special groups as research participants
Community engagement	Post-research access and benefit sharing	

2.1. Researchers must protect the dignity, rights, safety and well-being of research participants.

2.2. They should have appropriate qualifications, competence in research methodology and be compliant towards the scientific, medical, ethical, legal and social requirements of research.

2.3. The researcher, sponsor and EC must conduct a benefit–risk assessment and actively attempt to maximize benefits and minimize risks to participants.

2.4. Benefits to the individual, community or society refer to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.

2.5. Risk can be categorized as less than minimal risk, minimal risk, minor increase over minimal or low risk and more than minimal or high risk.

2.6. The EC must decide about the type of review required (exempted, expedited, full committee) based on the type of risk involved.

2.7. The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative (LAR) in writing.

2.8. Informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. These documents should be approved by the EC.

2.9. Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the EC.

2.10. Researcher(s) should safeguard the privacy and confidentiality of participants and research-related data from unauthorized access.

2.11. Benefits and burdens of research should be equitably distributed among the participating individuals or communities.

2.12. Participants should not be made to pay for research-related expenses incurred beyond routine clinical care. Reimbursement for expenses incurred can be made in cash or kind or both.

2.13. The researcher must report all serious adverse events (SAEs) to the EC within 24 hours of knowledge and submit a report on SAE relatedness to research within 14 days.

2.14. Research participants who suffer direct physical, psychological, social, legal or economic harm are entitled to financial compensation or other forms of assistance.

2.15. It is the responsibility of the sponsor (whether a pharmaceutical company, government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.

2.16. In investigator initiated/student research, the investigator/institution where the research is conducted becomes the sponsor and must provide compensation for research-related injury through insurance, corpus funds or grants.

2.17. Free medical care may be offered as ancillary care for non-research-related conditions or incidental findings if it does not amount to undue inducement as determined by EC.

2.18. Policies for declaration and management of financial or non-financial (personal, academic or political) conflict of interest for researchers, EC, institution and sponsor must be implemented by research institutes.

2.19. The selection of vulnerable and special groups needs careful consideration, with provisions for additional safeguards and close monitoring.

2.20. Engaging with the community from the beginning of research till after its completion helps to improve design and conduct of research and ensures greater responsiveness to health needs. However, every individual participant's consent is essential.

2.21. Post-research access and benefit-sharing may be done with individuals, communities and populations, wherever applicable after completion of study.

SECTION 3

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

3.1. Major components of RCR are values and policies; planning and conducting research; reviewing and reporting research; responsible authorship and publication aspects.

3.2. A research office must be set up to facilitate research, manage grants and provide research oversight.

3.3. Institutions must have policies for the protection of participants and should assign responsibilities to stakeholders.

3.4. Researchers must follow professional codes of conduct and have personal conviction about ethical requirements.

3.5. The following should be established prior to conducting research:

- Conflict of Interest policies
- Safeguards for data acquisition, management, sharing and ownership
- Policies for handling research misconduct including fabrication, falsification and plagiarism

3.6. Completed research, irrespective of results, must be published in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).

3.7. Clinical studies on human participants should be registered prospectively with the Clinical Trial Registry - India (CTRI). This is mandatory for regulatory trials.

3.8. Issues related to ownership, sharing of materials/data, IPR, joint publications, research findings, conflict of interest, commercialization should be addressed in collaborative research.

3.9. The ethical framework of international collaborations should be based on equity and equality. Researchers and EC members should be trained to protect the best interests of the country.

3.10. In multicentre research, common ethics review by a designated EC can help to reduce time for getting ethical approvals from across the sites and improve coordination among participating sites. However, the local EC must look at site specific concerns and monitor research.

ETHICAL REVIEW PROCEDURES

4.1. ECs must safeguard the dignity, rights, safety and well-being of research participants and review research before initiation.

4.2. The EC is responsible for scientific and ethical review of research proposals and should have well defined standard operating procedures (SOPs) for all functions.

4.3. Each member of the EC has a defined role and responsibility. EC members should be trained in protection of human research participants, SOP and Good Clinical Practice (GCP) guidelines, and be conversant with relevant ethical guidelines and regulations.

Composition, affiliations and qualifications given in Table: 3

Table 3: Composition, affiliations and qualifications of EC members

Members of EC	Qualifications
Chairperson/ Vice Chairperson (optional) Non-affiliated	• A well-respected person from any background with prior experience of having served/serving in an EC
Member Secretary/ Alternate Member Secretary (optional) Affiliated	• Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution
Basic Medical Scientist(s) Affiliated/ non-affiliated	• Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
Clinician(s) Affiliated/ non-affiliated	• Should be individual/s with recognized medical qualification, expertise and training
Legal expert/s Affiliated/ non-affiliated	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.
Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated	• Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
Lay person(s) Non-affiliated	• Literate person who has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community and aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities

4.4. The EC should be multidisciplinary, competent and independent in its functioning with the chairperson and 50% members as non-affiliates.

4.5. The quorum for decision-making should have a minimum of five members, including both medical and non-medical or technical/non-technical members with at least one of them as non-affiliated member.

4.6. EC members should be aware of local, social and cultural norms and emerging ethical issues.

4.7. Larger institutions can have more than one EC while smaller institutions may utilize the services of other institutions under an MoU.

4.8. An EC could have subcommittees with additional members, if necessary, e.g., SAE subcommittee or expedited review committee.

4.9. The institutional head appoints the EC and acts as the appellate authority.

4.10. The EC secretariat should screen proposals for completeness before categorizing as: exempted from review, expedited review or full committee review.

4.11. The EC reviews every study protocol for ethical issues as given in Table 4:

Table 4: Ethical issues related to reviewing a protocol

• Social values	• Scientific design and conduct of study
• Benefit–risk assessment	• Selection and recruitment of participants
• Payment for participation	• Protection of privacy and confidentiality
• Community considerations	• Review of informed consent process
• Disclosure of conflict of interest	• Qualification of researchers and adequacy of study sites
• Plans for medical management and compensation for study related injury	

4.12. The EC monitors progress of ongoing proposals, reviews SAEs, protocol deviations/ violations, new information and final reports.

4.13. An EC office must have space, infrastructure, funds, staff and protected time for the member secretary to coordinate EC functions.

4.14. EC documentation should be dated, filed and preserved. Records must be archived for at least 3 years (5 years for regulatory clinical trials) after completion/termination of the study.

4.15. ECs should be registered with the relevant authority and should make efforts to seek recognition or accreditation.

SECTION 5

INFORMED CONSENT PROCESS

5.1. Voluntary written informed consent should be obtained in an informed consent document (ICD) from each participant to protect each individual's freedom of choice.

5.2. Informed consent is a continuous process involving three main components:

- Providing relevant information to potential participants
- Ensuring competence and comprehension of the information and
- Voluntariness of participation

Table 5: Characteristics of an ICD

Elements of an ICD	Additional elements (optional)
1. Statement mentioning that it is research	1. Alternative procedures or treatment
2. Purpose and methods	2. Insurance coverage
3. Duration, frequency, methods	3. Possible stigmatizing condition
4. Benefits to participant, community or others	4. Biological material and data, including:
5. Foreseeable risks, discomfort or inconvenience	i) Current and future uses
6. Confidentiality of records	ii) Period of storage and secondary use
7. Payment/reimbursement for participation	iii) Sharing of data and biological materials
8. Treatment and/or compensation for injury	iv) Right to prevent use of biological sample
9. Freedom to participate/withdraw	v) Provisions to safeguard confidentiality
10. Identity of research team and contact persons	vi) Post-research plan/benefit sharing
	vii) Publication plan/photographs/pedigrees

5.3. Researchers should only use the EC approved version of the consent form and its translation in local languages.

5.4. Informed consent should be voluntary and be signed by the participant after receiving information, understanding it and discussing with family/friends (if required).

5.5. Verbal/oral consent/waiver of consent/reconsent may be obtained only after approval by the EC. Table 6 gives conditions for granting waiver of consent.

Table 6: Conditions for granting waiver of consent

The EC may grant consent waiver in the following situations:

- research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/data;
- certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

5.6. Appropriate ICD should be prepared for differently abled participants.

5.7. In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.

5.8. The LAR's consent is required in case a participant is incompetent (medically or legally).

5.9. Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and also if required for regulatory clinical trials.

5.10. Individual consent is important and required, even if the community gives permission for participation in a research study.

5.11. In studies using deception a true informed consent may lead to modification and may defeat the purpose of research. Such research should be carefully reviewed by the EC before implementation. In such instances, an attempt should be made to debrief the participants/communities after completion of the research.

VULNERABILITY

Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons. Individuals are considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and susceptible to exploitation
- Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
- Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent

6.1. Researchers must justify the inclusion/exclusion of a vulnerable population.

6.2. A community representative may be invited to EC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

6.3. Additional precautions should be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.

6.4. Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.

6.5. Research proposals should undergo review in a full committee meeting.

6.6. Protection of privacy and dignity as well as provision of quality health care is required in dealing with vulnerable people, especially the minorities.

6.7. Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.

6.8. Due approvals are needed from competent authorities before entering tribal areas.

6.9. Research involving cognitively impaired individuals or those with mental illness must be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

6.10. The EC should carry out the benefit–risk analysis and examine risk minimization strategies.

CLINICAL TRIALS OF DRUGS AND OTHER INTERVENTIONS

7.1. Clinical trials must be conducted in accordance with the Indian GCP guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), amendments to the Drugs & Cosmetics Act (1940), and Rules (1945) and other applicable regulations and guidelines.

7.2. Clinical trial interventions could be of drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health or socio-behavioural interventions, technologies, devices, surgical techniques or traditional systems of medicine, etc.

7.3. An investigator should determine if the clinical trial is within the regulatory ambit and if so, all Central Drug Standards and Control Organisation (CDSCO) requirements should be followed.

7.4. If students are conducting clinical trials as part of their thesis, guides/and institutions should take the responsibilities of sponsor.

7.5. Clinical trials must be prospectively registered with CTRI, which is mandatory for trials under the purview of CDSCO.

7.6. ECs should register and follow the quorum requirements specified by CDSCO before reviewing clinical trials on 'new drugs' as per Schedule Y and its amendments.

7.7. Patients should not be charged for trial interventions that are added on as part of research.

7.8. Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial.

7.9. Adverse effects of drugs should be reported in a timely manner.

7.10. Institutions must obtain grants, insurance coverage or set up corpus funds to meet the costs related to treatment/management and payment of compensation as decided by EC.

7.11. Clinical trials should be scientifically and ethically sound and preclinical studies should precede trials on humans.

7.12. BA/BE studies involving healthy volunteers may pose risks due to adverse effects of drugs and require safeguards.

7.13. Precautions should be taken to protect participants from harm when a placebo is used.

7.14. Trials on devices should follow the same requirements as for new drugs. Similarly, surgical interventions must also follow the ethical guidelines.

7.15. If a study involves biosimilars, the product quality, preclinical data and bioassay must demonstrate similarity with a reference biologic.

7.16. Clinical trials with stem cells should follow the National Guidelines for Stem Cell Research, 2017.

7.17. Community trials may be conducted to evaluate preventive strategies like mass drug administration.

7.18. Research that involves sexual minorities or intravenous drug users should ensure community engagement for the duration of the project as well as for dissemination of results after completion.

7.19. Research on traditional medicine interventions, such as Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) should be conducted in accordance with ethical guidelines, ASU-GCP (Ayurveda, Siddha, Unani GCP) guidelines as well as other applicable regulations.

7.20. Trials using diagnostic agents should follow the same protocols as for trials on new drugs.

7.21. Radioactive materials and X-rays should be used with more precaution in persons who have not completed family.

7.22. Clinical trials among women for contraceptives or if they are pregnant or lactating should involve abundant precautions and care.

7.23. Therapeutic misconception is high in oncology trials; therefore, due care should be taken to address this issue.

7.24. Any product using new technology should be GLP (Good Laboratory Practices), GMP (Good Manufacturing Practices) and GCP compliant, which should be duly approved by appropriate authorities.

PUBLIC HEALTH RESEARCH & SOCIAL AND BEHAVIOURAL SCIENCES RESEARCH FOR HEALTH

SECTION 8 & 9

[1]

8.1. Benefits and risks in public health research may not be limited to an individual, but may influence communities, populations and the environment.

8.2. Social and behavioural studies must ensure social equity and inter sectionality. Ethical relativism applies to moral diversity among different cultures and societies.

8.3. ECs must review different types of research such as programme evaluations, demographic surveillance, registries, implementation research, demonstration projects, community trials, surveys, etc.

8.4. Based on specific research, appropriate consent processes may be considered by the EC, such as verbal/oral consent; broad consent; group consent; waiver of consent and reconsent.

8.5. Special provisions should be provided in design and execution of research if they are likely to have a potential to exploit socioeconomically deprived people.

8.6. Stakeholders (researchers, health providers/ sponsors, Govt. agencies, participants, ECs, institutions, NGOs, etc.) must make every effort to provide post-research public health interventions, use of findings for sustainability of public health action.

8.7. The EC may require appropriate experts to address the specific ethical challenges related to socio-behavioural or public health research.

8.8. Safety measures should be in place to protect the privacy and confidentiality of research participants and/or research teams in the field collecting sensitive data.

8.9. The EC should carefully review studies where the use of deception is necessary to achieve the study objectives for larger public good and consider debriefing after completion of the study.

8.10. Support systems such as counselling centres, rehabilitation centres, police protection, etc. should be in place for sensitive studies.

8.11. The EC should ensure that the researcher has taken appropriate measures for data security and confidentiality of information and also that disclosure permissions have been taken and appropriate use of the accessed data is stated by the researcher.

[1] This section corresponds to Chapters 8 and 9 of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

HUMAN GENETICS TESTING AND RESEARCH

10.1. Due to an overlap between genetic research and services, therapeutic misconception is common and ethical, legal and social issues (ELSI) require careful consideration.

10.2. Genetic test results have familial/societal implications, therefore, maintaining confidentiality and providing pre- and post-test non-directive counselling by qualified persons is important.

10.3. Written consent should be obtained for genetic screening, confirmatory tests, specific interventions, pre-symptomatic testing, next generation sequencing, prenatal or carrier testing, genomic studies, use of embryos/foetal tissue, etc.

10.4. Informed consent should explain the nature and complexity of information, choices, implications, data/sample storage, etc.

10.5. If identifiable information is being collected for preparing family pedigrees, the members become secondary participants and informed consent should be obtained from each member.

10.6. Genetic screening should be purposive, with established provisions for disease management, treatment and counselling.

10.7. Genetic test reports of multifactorial/late onset diseases should be communicated carefully to prevent unnecessary worry or fear.

10.8. Information about a patient's disease and investigations may not be shared with others.

10.9. Screening for late onset diseases should not be done in children, unless there is suitable childhood intervention.

10.10. Technology should not be misused for pre-implantation genetic screening, creation of designer babies, sex selection, etc.

10.11. Confidentiality must be maintained while using new technologies like chromosomal microarray (CMA), whole exome sequencing, whole genome sequencing, etc.

10.12. Publication of pictures, pedigrees or other identifying information about individuals/ families requires fresh or re-consent.

10.13. Laboratories offering genetic testing should participate in quality assurance programmes specific to genetic testing.

SECTION 11

BIOLOGICAL MATERIALS, BIOBANKING AND DATASETS

11.1. Biological material may be prospectively collected or may be left over from earlier studies or clinical services, e.g. biological fluids, dried blood spots, tissues, organs, etc.

11.2. Datasets are collections of health data in disease registers, surveys, surveillance, census, personal records, etc.

11.3. Ethical issues such as ownership of samples or data, transfer of biospecimens, custodianship, secondary use, return of results, etc. are important.

11.4. Samples/data may be anonymous (unidentified); anonymized (coded reversibly or irreversibly) or identifiable.

11.5. Respecting ethnic identity and confidentiality is important in population-based studies/stigmatizing diseases.

11.6. Multiple layered consent provides options to allow samples/data to be used for future research. Types of consent include blanket or broad; tiered; specific; delayed; dynamic; waiver; re-consent, etc.

11.7. Informed consent should provide information about the commercial value of samples or data, if applicable, with clarity about benefit sharing.

11.8. Privacy and confidentiality should be ensured when databases are maintained in electronic/digital formats which are linked by Internet, cloud computing or are associated with big data initiatives.

11.9. Material transfer agreement (MTA) should be executed if the biospecimens are likely to be shipped to collaborators within or outside the country.

11.10. Data privacy, accuracy, security and legal liability should be clarified if the data is outsourced or sold.

11.11. Participants own their biological sample/data and biobanks/institutes are custodians or trustees.

11.12. A donor has the right to ask for destruction/withdrawal of collected sample(s).

11.13. Datasets and repositories offer huge potential for research as well as commercialization and the EC should review these aspects with caution.

RESEARCH DURING HUMANITARIAN EMERGENCIES AND DISASTERS

12.1. Pre-emptive research preparation can be done much in advance of a future humanitarian emergency by researchers and sponsors. Meticulous documentation and archiving are required to enable future application in similar situations.

12.2. Obtaining valid informed consent in an emergency situation is a challenge as the decision-making capacity is compromised in differentiating between reliefs offered and research.

12.3. Efforts should be made to protect the identifying information about individuals and communities to prevent stigmatization, ostracization and exploitation by the print and visual media.

12.4. Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled or unscheduled meetings and decided on a case-to-case basis.

12.5. If an expedited review is done, full ethical review should follow along with careful monitoring by the EC.

12.6. In case of an outbreak of infectious diseases, monitored emergency use of unregistered and experimental interventions (MEURI) may be approved with close monitoring.

12.7. Ongoing research may have to be suspended. This decision may be taken by researchers with information to the EC.

12.8. Prior arrangements about research questions to be addressed in the design, collection of samples, data sharing mechanisms etc. should be made in advance of an expected humanitarian emergency.

REFERENCE

1. National ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Research; 2017. Available from: https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (accessed 20 August 2018).
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8. Clinical Trial Registry-India[home page on the Internet]. Available from: www.ctri.nic.in
9. Guidelines for international collaboration /research projects in health research [home page on the Internet]. Available from: https://www.icmr.nic.in/content/guidelines
10. International guidelines for health related research involving humans. Geneva: Council for International Organizations of Medical Sciences; 2016.

STANDARD OPERATING PROCEDURES (SOPS)

S. No.	List of SOPs
1	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for ECs
2	Constituting an Ethics Committee
3	Confidentiality Agreements
4	Conflict of Interest Agreements
5	Training Personnel and EC Members
6	Selection of Independent Consultants
7	Procedures for Allowing a Guest or Observer
8	Categorization of Submitted Protocols for Ethics Review
	a. Initial Full Committee Review of New Research Protocols
	b. Expedited Review of Research Protocols
	c. Exemption from Ethics Review of Research Protocols
9	Agenda Preparation, Meeting Procedures and Minutes
10	Review of New Medical Device Studies
11	Review of Resubmitted Protocols
12	Review of Protocol Amendments
13	Continuing Review of Protocols
14	Review of Final Reports
15	Review of Serious Adverse Events (SAE) Reports
16	Review of Study Completion Reports
17	Management of Premature Termination, Suspension, Discontinuation of the Study
18	Waiver of Written or Verbal/oral Informed Consent
19	Site Monitoring Visits
20	Dealing with Participants' Requests and Complaints
21	Emergency Meetings
22	Communication Records
23	Maintenance of Active Study Files
24	Archive and Retrieval of Documents
25	Maintaining Confidentiality of EC's Documents
26	Reviewing Proposals involving Vulnerable Populations
27	Review and Inspection of the EC
28	Audio Visual Recording of the Informed Consent Process

HANDBOOK ON NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS

Dr. Vasantha Muthuswamy (Chairperson), Former Sr DDG & Head, Division of BMS, ICMR, New Delhi and President, Forum for Ethics Review Committees in India (FERCI)

Dr. Nandini K Kumar, Vice-President, Forum for Ethics Review Committees in India (FERCI)

Dr. Narendra K Arora, Executive Director, The INCLEN Trust International, New Delhi

Dr. Urmila Thatte, Prof & Head, Dept of Clinical Pharmacology, Seth GS Medical College, Mumbai

Dr. Vijay Kumar, Scientist 'G' & Head, Division of BMS, ICMR, New Delhi

Dr. Roli Mathur (Member Secretary), Scientist 'E' & Head, ICMR Bioethics Unit, NCDIR, Bengaluru

NCDIR Secretariat

Dr. Rajib Kishore Hazam, RA, ICMR Bioethics Unit, NCDIR, Bengaluru

Dr. Kalyani Thakur, RA, ICMR Bioethics Unit, NCDIR, Bengaluru

The aim of this handbook is to provide students, researchers and ethics committees a simplified reference to the “National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017”.

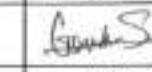
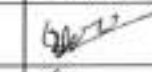
ICMR Bioethics Unit
National Centre for Disease Informatics and Research (NCDIR)
Indian Council of Medical Research
Poojanhalli Road, Off NH-7, Kannamangala Post, Bengaluru - 562110
Email: icmr.bioethics@gmail.com, www.ncdirindia.org

Indian Council of Medical Research
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110 029

ANNEXURE –II

SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES

TOPIC: ETHICS AND RESEARCH

SL.NO	STUDENT NAME ADDRESS	SIGNATURE
1	ELAVAZHAGHAN. R.	
2	GANESH. S.	
3	GAYATHRI.T.	
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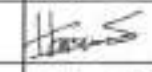
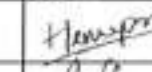
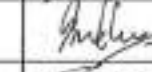
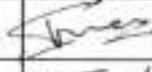
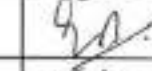
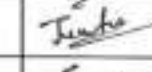
5	HARESH.S.	
6	HEMA PRIYA.K.	
7	INDHUJA. M.	
8	IREEN SUGITHA RANI.J.	
9	JAVEED IBRAHIM.J.	
10	JEEVIHA.R.	
11	JENIFER. R.	
12	JEYABHARATHI.K.	

ANNEXURE III

1. What is our general advice with respect to the concept of do no harm?

a. So long as you did not set out to harm participants you have nothing to worry about
b. Research that involves risk to participants should not be carried out by students
c. There are typically no hazards in student research studies.
d. None of the above

2. Which of the following apply to the use of a briefing sheet or participant information sheet?

a. Adult participants must be given the chance to understand the anticipated consequences of taking part in the study.
b. Children do not need to know the nature of the study as they are too young to understand.
c. Both A and B.
d. Neither A nor B.

3. What potential barriers to recruiting participants do we advise you to bear in mind when planning your sampling?

a. If you wish to work with young children you may need an enhanced Criminal Records Bureau disclosure or equivalent
b. Most undergraduate students are discouraged from collecting data in prisons or hospitals because of the additional ethical clearance and background checks required.
c. The timeframe for undergraduate projects may be too short to allow external ethical and legal clearances.
d. All of the above

4. Which of the following corresponds to our advice on ethical approval for your project?

a. Your study must be approved in full the first time you submit to the ethics committee, otherwise you will fail the project.
b. You must wait for ethics committee approval before beginning data collection.
c.Pilot work does not need ethical approval.
d. All of the above.

5. Which of the following is necessary in obtaining informed consent?

a. A description of the statistical analyses that will be carried out
b. A description of the purpose of the research
c. A description of the reliability and validity of test instruments
d. A list of publications that the researcher has had in the last ten years

6. Which of the following need(s) to be obtained when doing research with children?

a. Informed consent from the parent or guardian

b. Assent from the child if he or she is capable
c. Informed consent from the child
d. Both a and b

7. What is the primary approach that is used by the IRB to assess the ethical acceptability of a research study?

a. Utilitarianism
b. Deontology
c. Ethical skepticism
d. Comparativeism

8. Ideally, the research participant's identity is not known to the researcher. This is called:

a. Anonymity
b. Confidentiality
c. Deception
d. Desensitizing

9. There are three basic approaches that people tend to adopt when considering ethical issues in research. Which one of the following is not one of the approaches?

a. Ethical skepticism
b. Deontology
c. Ontology
d. Utilitarianism

10. IRB is an acronym for which of the following?

a. Internal Review Board
b. Institutional Rating Board
c. Institutional Review Board
d. Internal Request Board

SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATON AND RESEARCH

ETHICS & RESEARCH

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c. Institutional Review Board
d. Internal Request Board

ANNEXURE – IV

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research

(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that **GNANAKANNAN.G** has actively participated in the Value Added Course on **ETHICS AND RESEARCH** held during Mar 2018 – Aug 2018 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

DR.K. KANNAN MD,
RESOURCE PERSON,
ASSOCIATE PROFESSOR

DR.S.RAJINI MD,
COORDINATOR,
PROFESSOR & HOD,
DEPT OF COMMUNITY MEDICINE

DR.SUGUMARAN MD,
DEAN, SLIMS

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research
(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that **JEYABHARATHI .K** has actively participated in the Value Added Course on **ETHICS AND RESEARCH** held during Mar 2018 – Aug 2018 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

DR.K. KANNAN MD,
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ASSOCIATE PROFESSOR

DR.S.RAJINI MD,
COORDINATOR,
PROFESSOR & HOD,
DEPT OF COMMUNITY MEDICINE

DR.SUGUMARAN MD,
DEAN, SLIMS

Annexure v

Student Feedback Form

Course Name: **ETHICS IN RESEARCH**

Subject Code: **PSM01**

Name of Student: Elavarasan Roll No.: 1

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

SL NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
2	Course contents met with your expectations					✓
3	Lecturer sequence was well planned					✓
4	Lectures were clear and easy to understand				✓	
5	Teaching aids were effective				✓	
6	Instructors encourage interaction and were helpful				✓	
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

Excellent topics & Deliberation

Signature

Date: 02/06/18

Student Feedback Form

Course Name: **ETHICS IN RESEARCH**

Subject Code: **PSM01**

Name of Student: Gayathri. T Roll No.: 8

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
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5	Teaching aids were effective					✓
6	Instructors encourage interaction and were helpful				✓	
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

The course enhances & encourages us to participate in Research

Sighature

Date: 02/06/18

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY – 605 502

Date : 03.08.2018

From
Dr.S.Rajini
Professor and Head,
Department of Community Medicine,
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research,
Chennai.

Through Proper Channel

To
The Dean,
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research,
Chennai.

Sub: Completion of value-added course: ETHICS AND RESEARCH

Respected sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled: First aid management from March 2018 - August 2018 for Pre-final year students. We solicit your kind action to send certificates for the participants, that is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards,

Encl: Photograph