Dr. S. R. Chandrasekhar Institute of Speech and Hearing
(A unit of Bangalore Speech and Hearing Trust)
(A Project of Lions Club Bangalore East)
(Affiliated to Bangalore North University, recognized by Rehabilitation Council of India, New Delhi & B++ NAAC accredited)
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Institutional Code of Ethics for Research

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CONTENTS

1.0 INTRODUCTION

Dr. S. R. Chandrasekhar Institute of Speech and Hearing (Dr.SRCISH), Bangalore, is one of the leading clinical and academic Institutes in India. Dr.SRCISH was established in 1977, and since then has been dedicated to providing services to persons with communication disabilities, such as– patients with hearing impairment, voice disorders, stuttering, cleft lip, cerebral palsy, mental retardation, learning disability, autism spectrum disorders, and post-stroke communication disorders.

1.1 VISION

The vision of Dr. S. R. Chandrasekhar Institute of Speech and Hearing is to establish it-self as a center of excellence: A world without activity limitation for persons with communication disorders.

1.2 MISSION

The mission of Dr. S. R. Chandrasekhar Institute of Speech & Hearing is to work towards achieving the vision by:

- Developing a need for world-class human resources.
- Research that ensures human rights
- Develop clinical services that promote equal opportunities at affordable cost.
- Develop cutting edge science and technology to achieve our vision.
- Initiate preventive and pre-emptive action to avoid conditions leading to disabilities.
- Develop programmes in a whole life perspective and reduce the burden of family members of people with communication disorders.
- Create and provide infrastructure, laboratory, library and related facilities as stipulated by University and statutory bodies.

2.0 ETHICAL REVIEW AND APPROVAL

Practice and implementation of a policy on ethical review and approval is mandatory. Detailed description of sections related to ethical issues, constitution of ethical committee, objectives of ethical committee, standard operating procedures and formats for prospective research projects in the field of speech and hearing from Dr.SRCISH is outlined below.

2.1 ISSUES:

a) **Principle of Recognition and Respect for Human Rights**

b) **Principle of Privacy and Confidentiality** that protects privileged information of participating human subjects in bio-behavioral research investigations and to share entrusted information responsibly.

c) **Principle of Non-Exploitation** human participants should be remunerated for their involvement in the ongoing research activity. They should also be made aware of the risks involved irrespective of their socio-economic condition and education levels.

d) **Principle of Beneficence** which is the obligation of the research investigator to maximize benefits and minimize their potential risks for human participants.

e) **Principles of Provision of Maximal Safety** ensuring safety measures and research practices such as non-maleficence, beneficence, autonomy, fidelity and justice to the human participants participating in the research study.

f) **Principle of Professional Competency** requires the research projects/ investigations to be conducted by investigators with utmost experience, qualification and competent professionalism.

g) **Principle of Accountability and Transparency** that involves the research investigators to be answerable for their actions and decisions. The processes and decisions of the research investigations should be transparent and easily understood by the participants.

h) **Principle of Volunteerism** ensures the choice of participation of the human subjects in a research investigation to be entirely decided based on free will, choice and self-determination.

i) **Principle of Distributive Justice** signifies selection of human participants without discrimination based on caste, creed, socio-economic condition, religion, age, region, education etc ensuring that benefits and burdens are well distributed among the research population that are fair and just.

j) **Principle of Ethical Neutrality** ensures behaving in a respectful way towards, principles and values of the participants. This also makes sure that the participants are given a chance to be equally heard and accepted.

2.2 CONSTITUTION

The IEC shall consist of the following representatives

a) Chairperson:
   An eminent member of the Speech Language Pathology and Audiology discipline

b) Member Secretary:
   One faculty member not below the rank of any 'Head' among the Departments of Dr. SRCISH

c) External Members:
   At least three members representing the interests of human participants commonly involved in the field of speech and hearing research

d) Internal Member:
   One faculty member not below the rank of 'Head' among the Departments of Dr. SRCISH

e) Legal expert

f) NGO representative

g) Lay person Member:
   Administrator of the Dr. SRCISH

The chairperson as well as the internal and external members shall serve a term of three years. One third of the members will be replaced by new members after the completion of their term.
The IEC is intended to meet as needed at appropriate intervals. A quorum of at least five members is required for any IEC meeting. All decisions must be made by a majority vote of those present or, if voting by mail, by a majority of those qualified to vote. Attendance at IEC meetings is limited to internal, external, and invited members.

Project proposals received at least one month before the scheduled date of an IEC meeting will be considered for presentation on that meeting's agenda. The project's principal investigators or their designated representatives, as well as students/guides, are expected to make an appropriate presentation before the IEC and defend themselves against any doubts, clarifications, questions, suggestions, recommendations, or corrections offered by members thereof.

The Member Secretary shall notify the concerned principal investigator/s and students/guides in advance whose project/s are scheduled for review during a specific IEC meeting. Such prior information, as well as final acceptance or rejection of a study proposal, should be provided within fifteen days of the IEC meeting.

All IEC meeting minutes are to be coordinated, kept up to date, and organized by the Member Secretary. All details pertaining to project proposals that are received, examined, contested, changed, approved, or denied must be confidential. This also applies to any violations or trespasses committed by certain research investigators, as well as any fines or sanctions that the IEC may suggest in relation to specific cases that are brought up during the meetings. In the member secretary's office, IEC files pertaining to case inquiry and decision-making must likewise be kept confidential.

2.3 PURPOSE

The objectives of IEC are to:

a) Suggest any changes in the plan, procedure, sample, participants, methodology, use of instrumentation, research design, inclusion/exclusion criteria of a study, data collection procedures etc in as much as they violate the ethical guidelines enunciated here
b) Scrutinize, examine and review whether the research projects undertaken at the institute necessarily adhere to the guidelines proclaimed in this document.
c) Permit only approved and accepted research proposals to carry out the implementation of the permitted research activity at the institute
d) Take cognizance of any report of misconduct, error out of neglect or honest error of judgment in a research project at the institute brought to the notice of IEC and give suggestions to set right the mistakes
e) Safeguard the interests, rights and welfare of the human participants participating in the research activities at the institute.

2.4 SOP

The following guidelines are offered as Standard Operating Procedures (SOP) for the IEC:

a) A soft copy of research proposal for ethical clearance must be submitted in the prescribed format titled *"Form for seeking approval from IEC and undertaking by Principal Investigator"* and *"Format for Research Proposal, Informed Consent, and Participant*

Information Sheet" at least one month in advance a scheduled meeting of the IEC (Annexure 1 & 2)

b) The Member Secretary ensures that notice for the meeting of IEC, copies of research proposals along with its annexure and undertakings by the investigators are sent in advance to all the members of the IEC for their perusal.

c) Any difference/s of opinion/s between/ among the members of IEC regarding a particular proposal or research investigation must be clearly recorded in the minutes of the meetings. However, the decision of the Chairperson, IEC shall be final and enforceable.

d) The Member Secretary shall communicate in writing the final decision about acceptance/non-acceptance of a research proposal on behalf of the IEC to the principal investigator/s as soon as the decisions are available; but in any case, not later than fifteen days after conclusion of the meeting. A negative decision should always be supported by reasons as approved by the Chairperson, IEC.

e) The investigations into unethical conduct involve two types of investigations: 'show cause' proceedings and 'reviews' of alleged unethical conduct. The IEC may choose to deal with a matter according to either procedure and may convert an investigation from one type to another as appropriate. The IEC may also choose to dismiss an allegation or recommend that it be resolved with a reprimand or censure, with or without supplemental directives, etc.

f) IEC generally has no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving human subjects. They may, however, withdraw ethical approval of research projects if judged necessary. They can monitor implementation and progression. A failure to submit a protocol to the committee can be considered a serious violation of ethical standards.

g) Sanctions, if necessary, can be a recommendation to the institute and can be in the form of fines, suspension of eligibility to receive research funding, refusal of permission to publish results etc.

h) For case reports, the investigators must obtain a prior approval from the director and medical records officer (or equivalent) of the institute and the same should be submitted to the IEC for ethics approval.

2.5 FORMATS

The following formats are given as needed enclosures along with project proposals by principal investigators seeking clearance from IEC:

a) Form for seeking approval from IEC and undertaking by Principal Investigator (Annexure 1)
b) Research proposal format (Annexure 2)

3.0 MEMBERS OF INSTITUTIONAL ETHICS COMMITTEE (current members)

Chairperson
Dr. Prakash Boominathan
Professor and Principal
Sri Ramachandra Faculty of Audiology & Speech Language Pathology,
SRIHER (DU), Chennai
Chairperson, Dr. SRCISH Ethics Committee
Email: prakash_boominathan@sriramachandra.edu.in

Legal Expert:
Dr. Dhvani Mehta
Senior Resident Fellow
Vidhi Centre for Legal Policy

NGO Representative:
Dr. Shantha Radhakrishna
Director, Vagdevi Trust, Bangalore

Subject Experts:
Dr. CS Vanaja
Professor and Principal, BVU, Pune

Dr. Animesh Barman
Professor, AIISH, Mysore

Dr. Aravind Kumar
Associate Professor, NIMHANS, Bangalore

Dr. Sudhin Karupalli
Associate Professor, KMC, Mangalore

Internal Member:
Dr. Rashmi J Bhat
Professor and Principal, Dr. SRCISH

Lay Person Member:
Mr. Jayaram
Administrator, Dr. SRCISH

Member Secretary:
Dr. Avanthi Paplikar
Associate Professor and Research Coordinator, Dr. SRCISH

4.0 ANNEXURES

Annexure 1

Form for seeking approval from IEC and undertaking by Principal Investigator

IEC Ref. No. *(For office use):* *Date of submission:*

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable

b) where ever description/ detailed information is required, text boxes are provided, please type the information within that text box area.

c) Attach additional sheets if required

SECTION A – BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

	Name of Organization	
	Name of Department	
	Name of Candidate	
	Contact Details[2]	
	Type of Research Category	
	Course Name	
	Name of University	

Title of the study:

[1] *Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*

[2] *Include telephone/mobile, and email id*

SECTION B – RESEARCH INFORMATION

2. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words):

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health.	☐	Case Control	☐
Prospective	☐				
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative Data	☐	Biological samples/			
Mixed Method	☐	Any others *(Specify)*	☐		

3. METHODOLOGY

(a) Sample size/ number of participants *(as applicable):*

(b)

Control group/(s): Study group(s):

(c) Place of data collection : At Institute / At Other centers/ Online.

(d) Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

3 *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(e) How was the scientific quality of the study assessed by the research technical committee?

ii) Date of review by RTC:

iii) Comments of scientific committee, if any (100 words)

(f) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)*

.....

(g) Participant recruitment methods used:

Posters/leaflets/Letters	TV/Radio ads	Social media/ Institution website	Email/WhatsApp
Family/ Friends	Visiting hospitals		

Others *(Specify)* …….....……

(h) Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

(i) If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐

…….....

(j) Provide justification for inclusion/exclusion

(k) Are there any additional safeguards to protect research participants?

(l) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐

Provide details:

(m) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐

Provide details:

4. BENEFITS AND RISKS

(a) Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

(b) If yes, categorize the level of risk:

Less than Minimal risk ☐

Minimal risk ☐

Minor increase over minimal risk or low risk ☐

More than minimal risk or high risk. ☐

(c) Describe the risk management strategy:

(d) What are the potential benefits from the study?

For improvement in science:

5. INFORMED CONSENT

(a) Participant Information Sheet (PIS) is attached: Yes / No

(b) Informed Consent Form (ICF) is attached : Yes / No

(c) Type of consent :

Signed consent ☐ Verbal/Oral consent ☐

Witnessed consent ☐ Audio-Video (AV) consent ☐

(d) others (specify) .....

(e) List the languages in which translations were done:

(f) Provide details of consent requirements for previously stored samples (secondary data) if used in the study:

6. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. Yes □ No □ NA □

If Yes, specify:

(b) Anonymous/Unidentified □

(c) Anonymized: Reversibly coded □ Irreversibly coded □

(d) Identifiable □ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

(e) Who will be maintaining the data pertaining to the study?

(f) Where will the data be analyzed and by whom?

(g) For how long will the data be stored?

(h) Do you propose to use stored samples/data in future studies? Yes □ No □ Maybe □

If yes, explain how you might use stored material/data in the future ?

[7] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.*

7. DECLARATION BY THE RESEARCHER : (TO BE SIGNED)

DECLARATION (Please tick as applicable)	
✓	I/We certify that the information provided in this application is complete and correct.
✓	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
✓	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide- lines.
✓	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
✓	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
✓	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
	I/We declare that the expenditure in case of injury related to the study will be taken care of.
✓	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
✓	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
✓	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
✓	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
✓	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
	I/We have the following conflict of interest (PI/Co-I):
✓	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of candidate:

Signature and date:

Name of the guide:

Signature and date:

Name of the co-guide:

Signature and date:

Name of the HOD:

Signature and date:

Acknowledgement for Receipt of Application (Copy to be provided to PI)

This Form is adapted from DHR issued form template. https://www.naitik.gov.in/DHR/Homepage.

Annexure 2

Format for Research Proposal, Informed Consent, and Participant Information Sheet

RESEARCH PROPOSAL

(year)

PROPOSED TITLE

(Name)

(place)

Research Proposal

Guided by:

(guide's name)

(guide's designation)

Type of Study:

Title of the proposed research:

Background:

Need of the study:

Aim of the study:

Objectives of the study:

Method and Material:

Type of Study:

Participants:

Sample size:

Data collection:

Inclusion criteria:

Exclusion criteria:

Analysis of data:

Ethical considerations:

Results:

Management of the research across time/Gantt Chart

Problems anticipated:

Implications of the study:

References:

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Participant Information Sheet

Research Title:

Introduction:

Purpose of the study:

What will the study involve:

Risk and Benefits:

Do I have to participate:

Participation in this study is voluntary. If you agree to take part in this study, you will be asked to sign the "Informed Consent Form". You will be given a copy of the Information Sheet and the Consent Form.

If you wish not to participate in this study, your decision will be respected and you can withdraw without any penalty. In case you decide to withdraw sometime later, then your data will not be used and will be discarded.

Data and Confidentiality:

The data from this study will be made into a report which may be published. Access to the data will be only to the research team and Dr. S. R. Chandrasekhar Institute of Speech and Hearing. The data will be reported in a collective manner with no reference to an individual. Hence, the confidentiality of your identity will be maintained.

Payment and compensation:

You do not have to pay nor will you be paid for participating in this study.

Whom can I ask about the study:

If you have any queries, you can direct them to the researchers at Dr. S. R. Chandrasekhar Institute of Speech and Hearing for clarifications (Name, phone number and email).

Researcher name:

Dr. S. R. Chandrasekhar Institute of Speech & Hearing
Hennur Main Road, Bangalore - 560 084.
Tel: 080-25460405/25470037/25468470 Fax: 080-25467829
Email: dr.srcish@gmail.com Web: www.speechear.org

Informed Consent Form

Research Title:

Researcher's Name:

Brief summary of the study and its benefits to the participants

I,

- have read the information in the Participant Information Sheet including information regarding the purpose and procedure of this study
- have been given time to think about it and all of my questions have been answered to my satisfaction
- have given my consent for the audio-video recording to be taken, for the purpose of this research study
- understand that I may freely choose to withdraw from this study anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up

I voluntarily agree to be a part of this research study, follow the study procedures, and provide the necessary information to the researcher as requested.

(Signature) **(Date)**

***Informed consent to be taken in English and the language in which data will be collected.**