**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 with in that text box area.

 c) Attach additional sheets if required

#  SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

|  |  |  |
| --- | --- | --- |
| 1. | Name of Organization | Dr S R Chandrasekhar Institute of Speech and Hearing |
| 2. | Name of Department | NA |
| 3 | Name of Candidate |  |
| 4 | Contact Details2 |  |
| 4 | Type of Research Category | Dissertation for part fulfillment of PG course |
| 5 | Course Name | MSc Audiology/ MSc Speech Language Pathology |
| 6 | Name of University | Bangalore North University |

 (7) 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

1. OVERVIEW OF RESEARCH
	1. Lay summary3 (within 300 words):

 Type Information here

(b) Type of study:

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

..........................................................................................................................................................………............…………………................

1. METHODOLOGY
	1. Sample size/ number of participants *(as applicable):*

 e.g. Hearing Impaired group-30

* 1. Control group/(s) Study group(s)

 e.g. younger Age Group - 30

* 1. Place of data collection : At Institute / At Other centers/ Online.
	2. Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

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

* 1. How was the scientific quality of the study assessed by the research technical committee?
1. Date of review by RTC:
2. Comments of scientific committee, if any (100 words)

* 1. 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 | Patients |
| 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

1. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes □ No □
2. If yes, categorize the level of risk5:

 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 the Participant

For the society/community

 For improvement in science

1. . . 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 consentAudio-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 study7

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 6. STORAGE AND CONFIDENTIALITY

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

*If Yes, specify:*

1. Anonymous/Unidentified □
2. Anonymized: Reversibly coded □ Irreversibly coded □
3. 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.)
4. Who will be maintaining the data pertaining to the study?
5. Where will the data be analyzed9 and by whom?
6. For how long will the data be stored?
7. 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 ?

*7Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.*

*8Enclose undertaking from PI confirming the same*

 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):1. .....................................................................................................................................................................................................2. .......................................................................................................................................................................................................................................................................................................................................................................................................... |
| □ | I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable. |
| Name of candidate” ………………....................................................................................................................................……………...................... |
| Signature: ........................……………………………….............................................................................................Name of Guide: ..................................................................................................................................………………Signature: ........................……………………………….............................................................................................Name of C0-Guide: ..................................................................................................................................……………Signature: ........................……………………………….............................................................................................Name of HOD: ..................................................................................................................................………………Signature: ........................………………………………............................................................................................. | dd | mm | yy |  |
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|  |  |
| dd | mm | yy |  |
|  |

*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*](https://www.naitik.gov.in/DHR/Homepage)*.*