वसुधैव कुटुम्बकम्

SYMBIOSIS INTERNATIONAL (DEEMED UNIVERSITY)

(Established under section 3 of the UGC Act, 1956)
Re-accredited by NAAC with 'A++' Grade | Awarded Category – I by UGC
Founder: Prof. Dr. S. B. Mujumdar, M. Sc., Ph. D. (Awarded Padma Bhushan and Padma Shri by President of India)

Circular regarding constitution and functions of Institute Research Committee

CIRCULAR 6 OF 2023

Institute Research Committee (IRC) at each Constituent and its Functions

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WHEREAS Symbiosis International (Deemed University) had notified earlier Research Advisory Committee (RAC) at each Constituent. Later, the nomenclature of this committee was changed to Institute Research Committee (IRC).

AND WHEREAS, Research Advisory Committee continues at the University level for each Ph.D. scholar.

AND WHEREAS, the Institutional Ethics Committee in its meeting held on 27th October, 2023 suggested that the IRC be strengthened at the Constituent level;

AND WHEREAS, the earlier notified Institute Research Committee (IRC) has been revised with additional functions and new appendices.

NOW THEREFORE, in order to strengthen the role of Institute Research Committee (IRC) and promote research activities, each Constituent is hereby informed to constitute and activate the functions. Annexure A along with the application form and formats for writing research proposals for submission to IRC are attached herewith as appendices.

This is issued with the approval of the Competent Authority and will remain in force until further order.

॥वसुधैव कुटुम्बकम्॥
SIU

SIU/ U-11/2023/ 5314
Date: 31st October, 2023

Dr. M. S. Shejul
Registrar

N.B.: Please upload this Circular with the application form and formats for writing research proposals for submission to IRC on the Institute website. It will be available on the University website under Research.

Lavale, Pune 412 115, Maharashtra, India. | Tel.:+ 91-20-28116200 / 08 / 09 | Telefax. No.:+91-20-28116206
Email: info@siu.edu.in | Web: www.siu.edu.in

CIRCULAR 6 OF 2023

Institute Research Committee (IRC) and its functions

Symbiosis International (Deemed University) provides a conducive ecosystem for enriching research culture at all its Constituents. The faculty and students at the Constituents undertake research activities. In order to promote and monitor research activities, there shall be an **Institute Research Committee (IRC)** at each Constituent.

1. The composition of the Institute Research Committee (IRC) at the Constituent of the University shall be as under:

i)	Director/ Deputy Director	- Chairperson
ii)	One/ Two Professors/ Associate Professors	- Member
iii)	Two/ Three Subject Experts to be nominated by the Director of the Constituent	- Member
iv)	Assistant Professor Secretary	- Member

2. The tenure of the Committee shall be for a period of two years. Any vacancy arising during this period shall be filled in by the Director of the Constituent for the remaining period.

3. Meetings

i) The Committee shall meet as often as may be necessary but not less than four times during an academic year with two meetings in each semester. The meeting shall be presided by the Chairperson and in his absence the senior most Professor/ Associate Professor.

ii) The Member Secretary shall issue a notice of the meeting, at least seven clear days, before the date of the meeting. The Member Secretary shall send an agenda of the meeting to the members at least two clear days prior to the date of the meeting.

iii) Two thirds shall constitute the quorum for the meeting. If there is no quorum at the beginning of the meeting, the meeting shall be adjourned for half an hour on the same day or another day and there shall be no quorum required at such an adjourned meeting.

iv) The decision of the Committee shall be recorded in the form of resolutions. Every resolution shall be passed by majority.

4. Functions of Institute Research Committee (IRC):

The IRC shall have the following functions:

i) to review and approve field studies/ research projects/ research publications/ dissertations submitted by the degree students and faculty members;
ii) To advise/ forward research projects/ dissertations that may require approval of
iii) Institutional Ethics Committee of Symbiosis lnternational (Deemed University); to offer guidance for research projects/ research publications to students and faculty members;
iv) to promote ethical practices in research;
v) to encourage optimum utilization of resources for research;
vi) to set a target or research publications and assess research publications of faculty/ students;
vii) to understand the challenges and difficulties faced by the faculty/ students with respect to research publication
viii) to take stock of the ongoing research project and explore opportunities;
ix) to explore the research consultancy opportunities;
x) to explore research networking and collaborations;
xi) to plan FDPs/ training for faculty to build and enhance research outcomes;
xii) to organise conferences, FDP. student training towards excellence in research;
xiii) to encourage faculty for getting research grants from government agencies & industry / associations;
xiv) to foster interdisciplinary research;

Application Form and format for writing research proposal for submission to IRC are attached as appendices.

Appendix 1

To
The Chairperson
Institute Research Committee
(Name of the Institute)

Application for Review of Research Protocol / Project by IRC

(All the fields are mandatory. Mention 'NA' if item not applicable.)

A. Basic Information

1	Research Study Title	
2	Project ID / PRN (In case of PhD Scholar)	
3	Full Name of Principal Investigator (PI)	
4	Designation of PI	
5	Faculty / Department	
6	Name sponsor for the Research, if any	

B. Details about Co-Investigators

Sr. No.	Full Name of Co-Investigator	Designation	Affiliation
1.			
2.			
3.			
4.			
5.			
6.			

Documents for Application

The applicant should submit the following documents for a thorough and complete review:

1. The principle investigator should wright a covering letter to chairperson of the IRC including name of the principle investigator with designation and department to be mentioned. Name of the Institute/ Hospital where research will be conducted.
2. Approval letter from the Head of the Department.
3. Research Proposal
4. Informed Consent Document (In English & local language) Research tool
5. Ethical issues in the study and plans to address these issues.
6. Source of funding and financial requirements (if any) for the project.
7. An agreement to report only Serious Adverse Events (SAE) to IRC. (In case of clinical trial)
8. Statement of conflict of interest, if any.
9. Any other documents related to:
    a. National
    b. International (which has security clearance)
    c. Publishers requirement

Name of the Institute
INSTITUTE RESEARCH COMMITTEE
Format for writing Research Proposal

1.	**Name of the candidate and designation**	
2.	**Name of the Institution**	
3.	**Name of the program (in case of students)**	
4.	**Title of the proposal:**	
5	**Introduction:**	
6	**Need of the study:**	
7	**Objectives of the study:**	
8	**Research question:**	
9	**Hypothesis:**	
10	**Review of literature:**	
11	**Operational definition:**	
	Materials and methods:	
12	**Type of study:**	
13	**Population and Sample:**	

14	**Sample Size (Description of calculation):**
15	**Sampling technique:**
16	**Inclusion & exclusion criteria:**
17	**Tools and technique:**
18	**Inform consent document**
19	**Data collection method:**
20	**Data Analysis:**
21	**Gantt chart:**
22	**Details of funding/grant:**
23	**Study outcome:**
24	**References:**

Appendix II

Format of approval and recommendation by IRC to IEC

Name of the institution:

Project Title:

Principal Investigator:

Department:

Receipt of Proposal (Date)

Review (Date):

The Institutional Review Committee has received documents related to the above proposal and reviewed the following:

1. Review of Literature
2. Aims and Objectives
3. Methodology
4. Sample Size calculation
5. Method of Data analysis
6. Informed Consent Forms
7. Outcome
8. Any other document relevant to the study

We find the above in order, the proposal has been checked for Grammar and spellings too and has been found acceptable.

The Institutional Review Committee approves the proposal and suggests that the proposal may be recommended for a waiver/expedited approval/full board review by the Institutional Ethics Committee.

Signature

Name:

Chairperson IRC

Signature

Name:

Member Secretary IRC

Appendix III

Informed Consent Form

Date: ____/____/_____

Subject Identification Number:…….

Title of the study: ……...

Institute: …….

We are requesting you to participate in this research. Scientists at ……. will conduct this study. This consent form will provide you with the complete information about this study and about your participation required in the study. Please read the consent form carefully and if you have any questions, please feel free to ask.

Background information about the study: Government of India has aimed to eradicate ..... disease from India till ..... However, many patients do not have access to ..... Hence, GoI has lanuched ..... XYZ Institue is supporting GoI for effective implementation of the scheme.

Purpose of the study: In this study, we will try to understand..... The main objective of this study is to .....

Proposed activities: If you agree to participate in this study, you will be interviewed by the investigator. You will be asked questions about …… .. You will have to answer those questions. While answering some questions, you will have to pick one of the appropriate options. To answer some of the questions, you will not be given any options. This interview may take time period of … to … minutes. You will be required to undergo the following investigations during the study (Mention in brief about the investigations). You may be required to visit the Hospital / Laboratory for the investigation, and each visit may require about _____ minutes or hours.

Possible Benefits as an outcome of research: The study or its results are not likely to help you directly/may help you by helping us to treat you better/take better clinical decisions. Additionally, the study may lead to the development of more effective therapeutic strategies for the treatment of ……. patients. You will not receive any payment/reimbursement from your participation

in this study. (Please also mention about Free treatment and/or compensation of participants for research-related injury and/ or harm).

Possible / Any foreseeable risks, discomfort or inconveniences: By participating in this research study, it may or may not harm you / There are no additional risks involved. You may experience following risk/discomforts…

Confidentiality of records: Your study records will be kept confidential and would be used only for the purpose of research. Nobody outside the research team will have access to the information without your written authorization. Study information will be made available by the research team only to the authorized personnel involved in the study and the ethics committee.

Participation in the research study: Your participation in the study is purely voluntary and you are free to withdraw at any time, without giving any reason, without medical care or your legal rights being affected. You have the right to decide whether to take part in the research study or not. If you decide to take part in this study, you will be requested to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving any reason. Your withdrawal from the research study will not cause loss of any benefits or medical care, or your legal rights will not be affected.

If you have any queries about this study and about your rights as a research participant in this study or if you do not feel to provide any information about you; you may contact the Principal Investigator of this study at any time. The contact information of the Principal Investigator is provided below:

Principal Investigator:
Name:
Designation:
Department:
University:
Address:
Telephone:
E-mail:

Informed Consent by the participant:

The details of the study have been provided to me in writing and I have read all the information provided to me (Or the details of the study have been explained to me). I had opportunity to ask the questions or any doubts; and my all queries have been answered to my satisfaction, and all the doubts have been resolved. A copy of the Informed Consent Form has been given to me for my records. I understand that my participation in the study is voluntary, and that I am free to withdraw at any time, without giving any reason, without the benefit / medical care being affected or any of my legal rights being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I agree to take part in the above study.

Name of the participant: _____

Signature/Thumb impression of the participant:_____

Date: ____/____/_____

Name of the investigator:_____

Signature of the investigator: _____

Date: ____/____/_____

Informed Consent by Parent/Legally acceptable representative (LAR):

The details of the study have been provided to me in writing and I have read all the information provided to me (Or the details of the study have been explained to me). I had opportunity to ask the questions or any doubts; and my all queries have been answered to my satisfaction, and all the doubts have been resolved. I understand that my child/ward's participation in the study is voluntary, and that my child/ward is free to withdraw at any time, without giving any reason, without the benefit / medical care being affected or any of his/her legal rights being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is

only for scientific purpose(s). I fully consent for the participation of my child/ward in the above study.

(if applicable): I also consent to use my child/ward's collected or stored biological samples for future scientific purposes.

Name of the Child/Ward: _____

Name of the Parent / LAR: _____

Signature or thumb impression of the Parent / LAR: _____

Date: ____/____/_____

Name of the witness (if needed): _____

Signature or thumb impression of the witness: _____

Date: ____/____/_____

Name of the investigator:_____

Signature of the investigator: _____

Date: ____/____/_____

Assent by Children

(In case of interaction with children, a psychologist be present /validate with the vulnerable, as suitable or ICMR guideline compliance)

The details of the study have been provided to me in writing and I have read all the information provided to me (Or the details of the study have been explained to me). I had opportunity to ask the questions or any doubts; and my all queries have been answered to my satisfaction, and all the doubts have been resolved. I understand that my participation in the study is voluntary, and that I am free to withdraw at any time, without giving any reason, without the benefit / medical care or any of my legal rights being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I understand that following

completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Name of the child: _____

Age of the child: _____

Signature or thumb impression of the child: _____

Date: ____/____/_____

Name of the Parent / LAR: _____

Signature or thumb impression of the Parent / LAR: _____

Date: ____/____/_____

Name of the Investigator:_____

Signature of the Investigator: _____

Date: ____/____/_____

माहितीपूर्ण संमती फॉर्म

अनुक्रमांक: ☐

दिनांक: ____/____/_____

सहभागी व्यक्तीचा ओळख क्रमांक: ……..

संशोधन प्रकल्पाचे नाव: ……

संस्था: ……

या संशोधनात सहभागी होण्यासाठी आम्ही आपणाला विनंती करतो. …… येथील शास्त्रज्ञ डॉ. हा अभ्यास करणार आहे. हे संमती पत्रक आपल्याला या अभ्यासाबद्दल आणि अभ्यासात आवश्यक असलेल्या आपल्या सहभागाबद्दल संपूर्ण माहिती देईल. कृपया संमती पत्रक काळजीपूर्वक वाचा आणि आपल्याला काही प्रश्न असल्यास, कृपया आम्हाला विचारा.

प्रकल्पाची पार्श्वभूमी: भारत सरकारने …… पर्यंत …… हा आजार देशातून हद्दपार करण्याचे ठरविले आहे. …… परंतु भारतात अनेक रुग्नांना …… परवडत नाही. …… ही योजना प्रभावीपणे राबविली जावी यासाठी …… सरकारला मदत करत आहे.

प्रकल्पाचे उद्दिष्ट: …… हे या संशोधन प्रकल्पाचे प्रमुख उद्दिष्ट आहे. तसेच …… हेदेखील या संशोधन प्रकल्पाद्वारे समजून घेण्याचा प्रयत्न केला जाणार आहे.

संशोधन प्रकल्पाअंतर्गत ठरवलेली कार्ये : या संशोधन अभ्यासाअंतर्गत आपणाला …… संदर्भात काही प्रश्न विचारले जातील. या प्रश्नांद्वारे…… विषयी आपणाला असलेली माहिती, आणि याद्वारे मिळणाऱ्या लाभाचा कश्याप्रकारे उपयोग करून घेता हे जाणून घेण्याचा प्रयत्न केला जाईल. आपणाला या प्रश्नांची उत्तरे द्यायची आहेत. काही प्रश्नांची उत्तरे देताना, तुम्हाला योग्य पर्यायांपैकी एक निवडावा लागेल. काही प्रश्नांची उत्तरे देण्यासाठी, तुम्हाला कोणतेही पर्याय दिले जाणार नाहीत. या मुलाखतीचा कालावधी … ते … मिनिटांपर्यंत असू शकतो. या अभ्यासांतर्गत तुम्हाला खालील तपासण्या कराव्या लागतील (तपासण्यांविषयी थोडक्यात माहिती द्या). या तपासणीसाठी तुम्हाला हॉस्पिटल/दवाखाना/प्रयोगशाळेला भेट देण्याची आवश्यकता असू शकते आणि प्रत्येक भेटीसाठी सुमारे _____ मिनिट/तास लागू शकतात.

संभाव्य लाभ: या संशोधन प्रकल्पामध्ये आपण सहभागी झाल्यास आपल्या मुलाखतीमधून मिळालेल्या माहितीचा उपयोग …… मिळवून देणे व सदर लाभाचा प्रभावी उपयोग व्हावा यासाठी करण्यात येणार आहे. तुम्ही या अभ्यासामध्ये सहभागी झाल्यामुळे किंवा या अभ्यासाचे परिणाम तुम्हाला थेट

मदत करू शकत नाहीत/ तुम्हाला अधिक चांगल्या प्रकारचे उपचार देण्यास उपयुक्त ठरू शकतात. याव्यतिरिक्त, या अभ्यासामुळे अधिक चांगली, प्रभावशाली धोरणे विकसित होऊ शकतात/ या अभ्यासातील तुमच्या सहभागातून तुम्हाला कोणतेही पेमेंट/प्रतिपूर्ती मिळणार नाही. (कृपया सहभागी व्यक्तीला या संशोधनात सहभागी झाल्यामुळे होऊ शकणारी संबंधित इजा आणि/किंवा हानीसाठी सहभागींना जे मोफत उपचार आणि/किंवा नुकसान भरपाई दिली जाईल त्याबद्दल माहिती द्या.)

संभाव्य धोके: आपण या अभ्यासामध्ये सहभागी झाल्यास आपल्याला हानी पोहोचू शकते किंवा हानी पोहोचू शकत नाही / यात कोणतेही अतिरिक्त जोखीम नाहीत/ आपणाला कोणताही संभाव्य धोका नाही/ आपल्याला पुढील प्रकारचा त्रास/जोखीम / अस्वस्थता होण्याची शक्यता आहे...

गोपनीयता: आपली गोळा केलेली माहिती ही गोपनीय ठेवण्यात येईल आणि तिचा उपयोग केवळ संशोधनासाठीच करण्यात येईल. आपल्या लेखी संमतीशिवाय संशॊधन प्रकल्प समूहातील सहभागी व्यक्तींशिवाय इतर कोणालाही ही माहिती दिली जाणार नाही. या संशोधन प्रकल्पातून गोळा केली गेलेली माहिती ही या प्रकल्पामध्ये सहभागी असलेले, प्रायोजक आणि संशोधन आचारसंहिता समितीचे सदस्य यांपैकी केवळ अधिप्रमाणित व्यक्तींनाच दिली जाईल.

संशोधन प्रकल्पातील सहभाग:या प्रकल्पातील आपला सहभाग हा ऐच्छिक स्वरूपाचा असेल. या संशोधन प्रकल्पामध्ये सहभागी व्हायचे किंवा नाही हे ठरविण्याचा आपणास अधिकार आहे. जर आपण या संशोधन प्रकल्पामध्ये सहभागी व्हायचे ठरवले तर आपणाला संमतीपत्रावर सही करावी लागेल. आपण संमतीपत्रावर सही केल्यावरसुद्धा कोणत्याही क्षणी व कोणतेंही कारण न देता या संशोधन प्रकल्पातून आपला सहभाग काढून घेण्याचा आपणास अधिकार आहे. आपण या प्रकल्पातुन सहभाग काढून घेतलात तरी सरकारमार्फत आपणाला मिळणाऱ्या कोणत्याही सेवा आणि सुविधांवर याचा कोणताही विपरीत परिणाम होणार नाही. जर माहिती गोळा करत असताना मध्येच आपण आपला सहभाग काढून घेतलात तर आपली माहिती नष्ट करण्या येईल.

संपर्कासाठीची माहिती: आपणाला या प्रकल्पाबद्दल कोणत्याही स्वरूपाची शंका असल्यास, संशोधन अभ्यासातील सहभागी म्हणून आपल्या अधिकारांविषयी प्रश्न असल्यास किंवा आपल्याबद्दलची एखादी माहिती संशोधकाला देणे योग्य वाटत नसल्यास कोणत्याही क्षणी आपण या प्रकल्पाच्या प्रमुख संशोधकाला खाली दिलेल्या माहितीच्या आधारे संपर्क साधू शकता:

प्रमुख संशोधक:

नाव:

पद:

पत्ता:

संपर्क: लँडलाइन: मोबाइल:

ई-मेल:

सहभागी व्यक्तीद्वारे माहितीपूर्ण संमती:

या संशोधन प्रकल्पामध्ये सहभागी होण्यासाठी मला आमंत्रित करण्यात आले आहे. मला पुरविण्यात आलेली माहिती मी वाचली आहे, किंवा मला ती वाचून दाखवण्यात आलेली आहे आणि मला ती पूर्णपणे कळाली आहे. या प्रकल्पाविषयी काही शंका अथवा प्रश्न असल्यास ते विचारण्याची संधी मला देण्यात आली होती आणि मला त्या प्रश्नांची समाधानकारक उत्तरे देण्यात आलेली आहेत. मला जाणीव आहे की माझा ह्या प्रकल्पातील सहभाग ऐच्छिक स्वरूपाचा असून कोणत्याही क्षणी, कोणतेही कारण न देता आणि कोणत्याही प्रकारचा (कायदेशीर, वैद्यकीय, अथवा इतर)फायदा बाधित न होता, माझा सहभाग मागे घेण्याचा मला अधिकार आहे. जर या अभ्यासातून निर्माण होणारी माहिती किंवा परिणाम हे केवळ वैज्ञानिक हेतूसाठी वापरले जाणार असतील तर त्या माहिती किंवा परिणामांच्या वापरास मर्यादा न आणण्यास मी सहमत आहे. या प्रकल्पामध्ये सहभागी होण्यास माझी पूर्णपणे संमती आहे.

सहभागी व्यक्तीचे नाव: _____

सहभागी व्यक्तीची सही अथवा अंगठ्याचे निशाण: _____

दिनांक: ___/___/_____

संशोधकाचे नाव: _____

संशोधकाची सही: _____

दिनांक: ___/___/_____

पालक / कायदेशीररित्या मान्यताप्राप्त प्रतिनिधीद्वारे माहितीपूर्ण संमती:

या संशोधन प्रकल्पामध्ये सहभागी होण्यासाठी मला आमंत्रित करण्यात आले आहे. मला पुरविण्यात आलेली माहिती मी वाचली आहे, किंवा मला ती वाचून दाखवण्यात आलेली आहे आणि मला ती पूर्णपणे कळाली आहे. या प्रकल्पाविषयी काही शंका अथवा प्रश्न असल्यास ते विचारण्याची संधी मला देण्यात आली होती आणि मला त्या प्रश्नांची समाधानकारक उत्तरे देण्यात आलेली आहेत. मला जाणीव आहे की माझा पाल्ल्याचा या प्रकल्पातील सहभाग ऐच्छिक स्वरूपाचा असून कोणत्याही क्षणी, कोणतेही कारण न देता, कोणत्याही प्रकारचा (कायदेशीर, वैद्यकीय, अथवा इतर) फायदा बाधित ना होता, तसेच कोणत्याही स्वरूपाचा तोटा न होता, सहभाग मागे घेण्याचा त्याला / तिला अधिकार आहे. जर या अभ्यासातून निर्माण होणारी माहिती किंवा परिणाम हे केवळ वैज्ञानिक हेतूसाठी वापरले जाणार असतील तर त्या माहिती किंवा परिणामांच्या वापरास मर्यादा न आणण्यास मी सहमत आहे. या प्रकल्पामध्ये माझा पाल्ल्याने सहभागी होण्यास माझी पूर्णपणे संमती आहे.

(लागू असल्यास): माझ्या पाल्ल्याच्या घेतल्या गेलेल्या किंवा साठवलेल्या जैविक नमुन्यांचा वापर भविष्यातील वैज्ञानिक हेतूंसाठी करण्यास मी संमती देतो.

पाल्ल्याचे नाव: _____

पालक / कायदेशीररित्या मान्यताप्राप्त प्रतिनिधीचे नाव: _____

पालक / कायदेशीररित्या मान्यताप्राप्त प्रतिनिधीची सही अथवा अंगठ्याचे निशाण: _____

दिनांक: ___/___/_____

प्रत्यक्षदर्शी व्यक्तीचे नाव (गरज असल्यास): _____

प्रत्यक्षदर्शी व्यक्तीची सही अथवा अंगठ्याचे निशाण: _____

दिनांक: ___/___/_____

संशोधकाचे नाव: _____

संशोधकाची सही: _____

दिनांक: ___/___/_____

लहान मुलाद्वारे होकार:

या संशोधन प्रकल्पामध्ये सहभागी होण्यासाठी मला आमंत्रित करण्यात आले आहे. मला पुरविण्यात आलेली माहिती मी वाचली आहे, किंवा मला ती वाचून दाखवण्यात आलेली आहे आणि मला ती पूर्णपणे कळाली आहे. या प्रकल्पाविषयी काही शंका अथवा प्रश्न असल्यास ते विचारण्याची संधी मला देण्यात आली होती आणि मला त्या प्रश्नांची समाधानकारक उत्तरे देण्यात आलेली आहेत. मला जाणीव आहे की माझा ह्या प्रकल्पातील सहभाग ऐच्छिक स्वरूपाचा असून कोणत्याही क्षणी, कोणतेही कारण न देता आणि कोणत्याही प्रकारचा (कायदेशीर, वैद्यकीय, अथवा इतर)फायदा बाधित न होता, माझा सहभाग मागे घेण्याचा मला अधिकार आहे. जर या अभ्यासातून निर्माण होणारी माहिती किंवा परिणाम हे केवळ वैज्ञानिक हेतूसाठी वापरले जाणार असतील तर त्या माहिती किंवा परिणामांच्या वापरास मर्यादा न आणण्यास मी सहमत आहे. या प्रकल्पामध्ये सहभागी होण्यास माझी पूर्णपणे संमती आहे.

पाल्ल्याचे नाव: _____

पाल्ल्याचे वय : _____

पाल्ल्याची सही अथवा अंगठ्याचे निशाण: _____

दिनांक: ___/___/_____

पालक / कायदेशीररित्या मान्यताप्राप्त प्रतिनिधीचे नाव: _____

पालक / कायदेशीररित्या मान्यताप्राप्त प्रतिनिधीची सही अथवा अंगठ्याचे निशाण: _____

दिनांक: ___/___/_____

संशोधकाचे नाव: _____

संशोधकाची सही: _____

दिनांक: ___/___/_____

Appendix V

Types of IEC review

Sr. No.	Types of review	
1	**Exemption from review**	Proposals with less than minimal risk where there are no linked identifiers, for example; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	**Expedited review**	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in

		researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • for multi-centre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters (See Section 12 for further details).
3	**Full committee review**	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk (see Table 2.1 for further details); • studies involving deception of participants (see section 5.11 for further details); • research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but not limited

		to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.