**AVINASHILINGAM INSTITUTE FOR HOME SCIENCE**

**AND HIGHER EDUCATION FOR WOMEN**

**COIMBATORE – 641043, India**

**Application for Review of Project Proposal by the**

**Institutional Human Ethics Committee**

For student research projects and non-student, non-clinical trial projects

**Note:** Read this APPLICATION FORMAT completely before you start filling it. Do not leave any items blank. If any item is not applicable to your study, write “Not Applicable” or “NA” against that item. We request you to use the soft copy of this format and submit the printout of a word-processed application (three hard copies and one soft copy on CD).

1. **Background Information**
2. **Title of your proposed research project (fill in the box below):**

|  |
| --- |
|  |

1. **Brief profile of those involved in the project:**

**2(a) To be filled in for Student Projects :**

Name of the Student (Principal Investigator) :

Course of Study and year :

Name of the Supervisor :

Contact Number (mobile) :

E-mail Id :

|  |  |
| --- | --- |
| ***For office use only*** | **IHEC Application No.** |
| Date of Receipt of application in the IHEC: |  | **IHEC SEAL**: |
| Date forwarded to IHEC (Primary Reviewer): |  |
| Date forwarded by IHEC to Reviewers: |  |
| Date of IHEC Panel Review, if applicable: |  |
| Date of despatch of approval letter by IHEC: |  |

**2(b) To be filled in for non-Student Projects (within our University):**

Name of the Principal Investigator :

Designation :

Department where the study is to be executed :

Is the project funded by external agency? : □ Yes □ No

If yes, Name of the agency :

Contact Number (mobile) :

**2(c) To be filled in for non-Student Projects (external members):**

Name of the Principal Investigator :

Academic Qualifications :

Designation and Department :

Institution where the study is to be executed :

Reason(s) for submission to our University for ethical clearance:

Is the project funded by external agency? : □ Yes □ No

If yes, Name of the agency :

Contact Number (mobile) :

1. **Particulars about the proposed project**
2. **Background of the project:**

3(a) Introduction (brief, in 4 – 5 lines)

3(b) Review of literature (brief, in 3 – 4 paragraphs; include at least 5 key references; provide complete reference list at the end of this section, with a brief summary of each reference, highlighting how the study relates to your work)

1. **Objectives of the study:**

4(a) Primary Objectives:

4(b) Secondary Objectives:

1. **Methodology of the study:**

5(a) Layout of the study involving human participants / data (Please enclose a flow-chart)

5(b) Type of data to be generated in the study:

 Are you going to

 Collect data afresh from the study-volunteers? □ Yes □ No

**or**

 Collect pre-existing data from case-sheets/other sources? □ Yes □ No

5(c) Data Collection Tool to be used : (Forms / Questionnaire etc)

 Specimen Copy to be enclosed.

5(d) Area / Location of the study :

5(e) Type of study population :

5(f) Does the study involve sampling : □ Yes □ No

 If Yes,

 Size of study sample :

 Estimation of study size :

 Age group of study sample :

 Gender : □ M □ F □ B □ T

 [M-male; F-female; B-both male and female; T-transgender]

 Sampling Method :

 Inclusion Criteria:

 Exclusion Criteria:

1. **Duration of the study :**
2. **Proposed date of commencement of the study :**
3. **Evaluation Plan proposed:**

[Outline how the aims of the study will be measured / what will be considered as success or otherwise, of the study]

1. **Dissemination of the findings of the study: [Tick as many as applicable]**

□ Scientific meets (Conferences / Seminars etc.)

□ Departmental review meets

□ Doctoral Committee

□ Publications

□ Thesis

□ Project report to funding agency

□ Other (Please specify)

1. **Does the study involve collection of biological material?** □ Yes □ No

If yes,

Type of sample to be collected (blood, urine, etc.) :

Quantity of sample to be collected :

Size of the collection : □ From all study volunteers

□ From a sub-sample of size \_\_\_\_\_\_\_

Parameter(s) to be estimated in the biological sample:

1. **Are you informing the study participants that the biological samples collected will be used for the stated purpose only?**

□ Yes □ No □ Not applicable

1. **Do you anticipate any risk to the study volunteers?** □ Yes □ No

If yes, what type of risk is anticipated?

1. **What are the benefits from this study, if any, to the study volunteers?**
2. **Who will fund your project expenses? (Enclose relevant documents)**
3. **Conflict of Interest, if any :**

**D E C L A R A T I O N**

I/We hereby declare that I/We have completed all sections of this application and attached all the required documents as described in the ‘Checklist of Documents to be attached with Application for Review by IHEC’. I/We further declare that all information provided in this application and its attachments are true to the best of my/our knowledge and belief. I/We understand that the approval to this study will be cancelled if I/we have provided any wrong information or withheld relevant information from this application. I/We assure that my/our project entitled (write the title of your project) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, if approved by the Institutional Human Ethics Committee of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore, will be carried out by adhering to the plan described in this application, and that any deviation from the same will be communicated to the IHEC in writing. I/We understand that deviation from the study plan described in this application without informing the IHEC shall result in the cancellation of approval.

**Name(s) and Signature(s) of the Investigator(s) & Supervisor(s) involved in this project:**

**Investigator**:

Name: Signature:

 Date:

**Supervisor**:

Name: Signature:

 Date:

**Head of the Department**:

Name: Signature:

 Date:

**INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS**

(strike off items that are not applicable)

I / We (write name(s) of the investigator(s) here), \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ am / are carrying out a study on the topic \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

as part of my / our research project being carried out under the aegis of the Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

My / our research guide is:

(Applicable to students only)

The justification for this study is:

The objectives of this study are:

Primary Objective(s):

Secondary Objective(s):

Sample size: \_\_\_\_\_\_\_\_\_\_.

Study volunteers / participants are (specify population group & age group): \_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Location of the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview (specify approximate duration):\_\_\_\_\_\_ minutes.

Data collected will be stored for a period of fifteen years. We will / will not use the data as part of another study.

Health education sessions: Number of sessions: \_\_\_\_\_\_\_\_\_\_\_\_\_.

Approximate duration of each session: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ minutes.

Clinical examination (Specify details and purpose):

Blood sample collection: Specify quantity of blood being drawn: \_\_\_\_\_\_\_\_\_ml.

No. of times it will be collected: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Whether blood sample collection is part of routine procedure or for research (study purpose):

□ Routine Procedure □ Research Purpose

Specify purpose, discomfort likely to be felt and side effects, if any:

Will the blood sample collected be stored after study period: □ Yes

□ No, it will be destroyed

Will the blood sample collected be sold: □ Yes □ No

Will the sample collected be shared with persons from another institution: □ Yes □ No

Medication / supplementation given, if any, with duration, side effects, purpose, benefits:

Is the medication / supplementation given part of routine procedure: □ Yes □ No

(If no, state reasons for giving this medication/supplementation)

Are alternatives available for medication / supplementation given: □ Yes □ No

(If no, state reasons for giving this particular medication/supplementation)

Final interview (specify approximate duration): \_\_\_\_\_\_\_\_\_ minutes.

If photograph is taken, purpose:

Benefits from this study, if any :

Risks involved by participating in this study, if any :

How will the results be used:

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, you have the right to withdraw from the interview / study at anytime. You have the freedom to withdraw from the study at any point of time. You will NOT be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings – including adverse events, if any – whether directly or indirectly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation

**Consent**: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator(s). Having understood the same, I hereby give my consent to them to interview me, and collect biological sample \_\_\_\_\_\_\_ from me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements)

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date

Signature of the Witness with name:

**Checklist of Documents to be attached with Application for Review by IHEC**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl. No.** | **Document** | **Yes** | **No** | **NA\*** |
| 1 | Duly filled in application for review by the IHEC (all sections must be complete) |  |  |  |
| 2 | Project Timeline/ Gantt Chart showing week-wise activities for the whole study period |  |  |  |
| 3 | Copy of Letter granting funds / Studentship / Scholarship / Fellowship (if applicable) |  |  |  |
| 4 | Permission letter from the head of the institution from where data is to be collected |  |  |  |
| 5 | Informed Consent Form in English  |  |  |  |
| 6 | Informed Consent Form translated into the relevant language(s) |  |  |  |
| 7 | Patient Information Sheet in English, if applicable  |  |  |  |
| 8 | Patient Information Sheet translated into the relevant language(s), if applicable |  |  |  |
| 9 | Confidentiality Statement |  |  |  |
| 10 | Data collection tool (Questionnaire / form, etc.) in English [Please enclose sample copy] |  |  |  |
| 11 | Data collection tool (Questionnaire / form, etc.) translated into the relevant language(s) [Please enclose sample copy] |  |  |  |
| 12 | Current CV of the Principal Investigator and / or Supervisor |  |  |  |
| 13 | All relevant pre-clinical animal data |  |  |  |
| 14 | Compensation for study participation |  |  |  |
| 15 | Any other information relevant to the study (Provide list)  |  |  |  |

**\* NA = Not Applicable**

[Note: Please respond to all the above items in the relevant boxes. Do not leave any item unmarked]