Covering letter for IEC Review

**To,**

**The Member Secretary,**

**Institutional Ethics Committee,**

**HIMSR, New Delhi**

Subject: Request for **Full Review / Expedited Ethical/ Exemption** (select one) of Research Proposal

Respected Sir/Madam,

I, ………., (designation) at Department of …….., wish to submit my research proposal titled “……………….” for consideration under **Full Review** **/ Expedited Ethical/ Exemption** (select one) by the Institutional Ethics Committee of HIMSR.

My research proposal has been duly reviewed and approved by the Research Project Advisory Committee (RPAC) on ..../…../.. (**attach RPAC approval letter**)

The study will be conducted at ……….. (mention study site) and involves the collection of (mention samples). The procedure ***dose/does not*** involve the collection of any additional samples beyond routine collection.

Given the (select one)

***Less than minimal risk***

***Minimal risk***

***Low risk***

***More than minimal risk or High risk***

involved in my study and its compliance with ethical guidelines, I kindly request an (select one)

***Full******Review***

***Expedited Ethical (Attach Annexure I- see next page)***

***Exemption (Annexure II - see next page)***

under the applicable ethical framework. (*Kindly give reason for your selection of risk – See table 1 of* *HIMSR IEC SOP* *Page 29*)

Enclosed with this application are the following documents for your kind perusal:

1. Copy of RPAC approval letter

2. Study Protocol

3. Participant information sheet and informed consent form (English & Hindi)

4. Case Report Form / Questionnaire / Data extraction form

5. Check List for Protocol Submission

6. Copy of approval letter from other IEC (If present)

I assure you that the study will be conducted in strict adherence to ethical guidelines and with utmost regard for participant safety and confidentiality.

Thank you

PI name and designation

Sign with date

PI Email:

PI Contact No.:

**Annexure I. Application Form for Expedited Review**

Title of study:

Principal Investigator (Name, Designation and Affiliation):

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| --- |
| Choose reasons why expedited review from EC is requested? |
| i. Involve non-identifiable specimen and human tissue from sources like bloodbanks, tissue banks and left-over clinical samples |  |
| ii. Involve clinical documentation materials that are non-identifiable (data, documents, records). |  |
| iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s) |  |
| iv. Revised proposals previously approved through expedited review, full review, or continuing review of approved proposals |  |
| v. Minor deviations from originally approved research causing no risk or minimal risk |  |
| vi. 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. |  |
| vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre. |  |
| viii. Research during emergencies and disasters |  |
| ix. Any other (please specify) |  |
| 1. Is waiver of consent being requested ? | Yes | No |
| 2. Does the research involve vulnerable person? | Yes | No |
|  If yes, give details: |  |  |

PI name and designation

Sign with date

PI Email:

PI Contact No.:

**Annexure II. Application Form for Exempted Review**

Title of study:

Principal Investigator (Name, Designation and Affiliation):

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| --- |
| Choose reasons why Exempted review from EC is requested\*? |
| i. Research on data in the public domain (data depository or data available from surveys and research - NFHS) |  |
| ii. Systematic reviews or meta- analyses |  |
| iii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person |  |
| iv. Quality control and quality assurance audits in the institution (where there are no individual identifiers) |  |
| v. Comparison among instructional techniques, curricula, or classroom management methods (where there are no individual identifiers) |  |
| vi. Consumer acceptance studies related to taste and food quality |  |
| vii. Public health programmes by government agencies (where there are no individual identifiers) |  |
| viii. Any other (please specify in 100 words): |  |

Signature of PI:

Comments of EC Secretariat:

Signature of Member Secretary: