**Annexure 1**

**AX1-V6/SOP04c/V6**

**Review Exemption Application Form**

TMC Project No. :\_\_\_\_\_\_\_\_\_\_\_\_(To be filled by IEC Secretariat)

1. Principal Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Department/ Disease Management Group (DMG): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Title of Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Names of study team members: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, study population, and procedures/methods to be used in the project.

Please check that your application / summary includes:

* Procedures for voluntary, informed consent
* Privacy & confidentiality
* Risk to participants
* Needs of dependent persons
* Conflict of interest
* Permission for access to participants from other institutions or bodies
* Inducements

1. State reasons why exemption from IEC review is requested? (Tick applicable)

* Audit of educational practices
* 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;
* Research on microbes cultured in the laboratory
* Research on immortalized cell lines
* Research on cadavers or death certificates which reveals no identifying personal data
* Analysis of data freely available in the public domain for systematic reviews or meta-analysis;
* 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).
* Any other (please specify) -------------------------------------------------------

**Principal Investigator’s signature:** \_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_

**Forwarded by the Head of the department:**

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Forwarded by the DMG Convenor/Secretary:**

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Recommendations by the IEC Member Secretary:**

* + - Exemption, Reasons \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
    - **Can not be** exempted, Reasons \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* + - Discussion at full board

**Signature of the Member Secretary: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Final Decision:

* + - Exemption
    - Cannot be exempted,

Reasons \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* + - Discussion at full board

**Signature of the Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Final Decision at Full Board meeting held on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**