

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 multicentre 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

Source: National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 of Indian Council of Medical Research (ICMR) available at https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf assessed Jan 5, 2021.