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REPORT

Responsible researchers and reviewers: Ethics of Good Clinical Practice silver jubilee workshop report

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Abstract

Ethics education in biomedical research in India is frequently limited to regulatory compliance, with inadequate emphasis on ethical reasoning, contextual vulnerability, and deliberative review processes. As part of the Silver Jubilee of the Institutional Ethics Committee of St John's Medical College Hospital, a one-day preconference workshop titled "Responsible Researchers and Reviewers: Ethics of Good Clinical Practice" was conducted during the 13th International Conference of Ethics Education. The workshop employed case-based, interdisciplinary discussions focusing on vulnerability, ethics committee accreditation, and ethical review of diverse study designs. Key gaps identified included difficulties in operationalising vulnerability, managing surrogate consent in critical care research, inconsistent ethics committee monitoring practices, and limited faculty preparedness for ethics pedagogy. The discussions revealed a need to move beyond knowledge transmission towards reflective, skills-based ethics education.

Keywords: *research ethics, ethics committees, ethics education*

Ethical conduct in biomedical research is foundational to public trust, participant protection, and scientific integrity. In India, despite robust regulatory frameworks — including the Indian Council of Medical Research (ICMR) National Ethical Guidelines and mandatory ethics committee oversight — ethics education often remains fragmented and procedural. Training programmes frequently emphasise regulatory requirements rather than cultivating ethical reasoning, reflexivity, and context-sensitive decision-making among researchers and reviewers. This gap becomes particularly pronounced in complex research contexts such as paediatric studies, adolescent health, critical care research, and multi-centric trials.

Against this background, the Institutional Ethics Committee (IEC) of St John's Medical College Hospital organised a focused workshop to critically examine the ethical responsibilities of researchers and reviewers, with an emphasis on Good Clinical Practice (GCP), vulnerability, and ethics committee (EC) processes.

The workshop adopted an interactive, discussion-driven pedagogic model, deliberately moving away from didactic lectures toward case-based ethical deliberation. Participants included faculty members, postgraduate students, researchers, and ethics committee members from diverse institutional settings. Ethical principles were consistently examined through real-world scenarios rather than abstract normative frameworks. Ethics committee members participated as facilitators, reinforcing the notion of ECs as educational stakeholders rather than solely as regulatory authorities.

Historical milestones such as the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report were revisited, not as static doctrines but as evolving responses to ethical failures. Participants acknowledged that regulatory familiarity does not necessarily translate into ethical sensitivity, particularly when dealing with uncertainty, competing interests, or power asymmetries. A recurring concern was the tendency to equate ethics with documentation.

Accreditation was perceived as a mechanism to improve transparency, consistency, and accountability in EC processes, particularly in documentation, conflict-of-interest management, and study monitoring. However, participants expressed concerns about resource constraints, especially in smaller institutions, and the risk of accreditation becoming a checklist exercise rather than a driver of ethical culture.

Case-based discussions on neonates, adolescents, women, and critically ill adults revealed a persistent ambiguity in defining and operationalising vulnerability. Participants struggled to balance protection with access to potential benefits, particularly in neonatal and paediatric research. Parental consent may be influenced by stress, therapeutic misconception, and power differentials [1]. Adolescent research raises tensions between emerging autonomy, confidentiality, and parental authority [2]. In critical care research, surrogate consent, deferred consent, and post-trial access were identified as ethically complex and inadequately addressed in routine training [3].

Panel discussions emphasised that ethics review does not end with the approval of protocols. The challenges identified included delayed reporting, inconsistent monitoring, and limited training in serious adverse event causality assessment.

Despite high baseline knowledge among participants, the discussions revealed gaps in applied ethical reasoning, particularly in translating principles into practice. It was noted that limited formal training in ethics pedagogy resulted in reliance on personal experience rather than structured teaching frameworks. The workshop was limited

by its single-day duration, which constrained the depth of discussion and follow-up. Participant representation, though interdisciplinary, may not reflect the diversity of institutions nationally.

At the institutional level, ethics education should be integrated longitudinally into undergraduate, postgraduate, and faculty development programmes with ethics committees as educational hubs. Accreditation frameworks should prioritise ethical culture and deliberative capacity over procedural compliance.

This workshop highlighted that strengthening ethics in clinical research requires moving beyond regulatory literacy toward sustained, context-sensitive ethical engagement. Case-based, interdisciplinary learning offers a valuable pedagogic approach but must be embedded within institutional and national strategies for ethics capacity building. The reflections presented here underscore the need for longitudinal training, faculty development, and policy support to nurture ethically responsible researchers and reviewers.

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