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Research Article

# Research Ethics Governance and Responsible Conduct of Research at the Defence Services Medical Academy, Myanmar: A Documentary Analysis

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## Abstract

Ethical Review Committees (ERCs) require both formal governance mechanisms and continuing capacity building to support consistent ethical review and responsible research conduct. The Defence Services Medical Academy (DSMA), Myanmar, has maintained institutional standard operating procedures (SOPs) for its Ethical Review Committee and has conducted recurring workshops on responsible conduct of research (RCR). To describe the longitudinal evolution of research ethics governance and RCR capacity building at DSMA using available institutional documentary sources. A retrospective descriptive documentary analysis was undertaken using available DSMA ERC SOPs dated 2017 and 2022, a separate 2022 SOP for principal investigators, the 2024 third-edition SOP, and RCR/research-ethics workshop programmes from 2018, 2022, 2023, 2024 and 2026. Documents were reviewed using predefined domains: governance and committee structure; review procedures; participant protection; informed consent; post-approval oversight; investigator guidance; data and material governance; documentation; and research-ethics capacity building. Changes were interpreted as documentary evidence of formalization, differentiation or expansion; no causal inference regarding research quality or participant outcomes was made. The documentary series demonstrated progressive formalization of ERC governance and expansion of operational guidance. The 2017 SOP already addressed committee functions and composition, vulnerable participants, review procedures, informed consent, expedited review, decision-making, monitoring and archiving. By 2022, the institutional SOP incorporated specific guidance for medical education and genetic research and additional operational forms, while a separate PI-oriented SOP provided investigator-facing guidance and multiple consent templates. The 2024 third edition reorganized the SOP into thematic chapters and expanded guidance for survey, records, qualitative and genetic research; waiver of consent; material transfer; data ownership/transfer/use; conflict-of-interest declaration; annual reporting; and final reporting. In parallel, RCR workshops documented from 2018 through 2026 repeatedly addressed research integrity, informed consent, data ethics, research misconduct and investigator responsibility, frequently using group work and discussion. Available documents indicate an evolution at DSMA from a broad institutional ethics-review framework toward a more differentiated governance system combining committee procedures, investigator guidance, research-specific ethical considerations, post-approval documentation and recurring RCR education. Future evaluation should assess implementation, review performance, investigator competence, protocol quality and outcomes of post-approval oversight.

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## Keywords

Ethical Review Committee, Ethical Review, Standard Operating Procedure, Responsible Conduct of Research, Research Governance, Capacity Building, Documentary Analysis, Myanmar

# 1. Introduction

Ethical review is a core component of systems designed to protect the dignity, rights, safety and well-being of people participating in health-related research. International guidance emphasizes that research ethics committees should operate within a broader system that supports independence, transparent procedures, appropriate membership, continuing education, written policies, record keeping and ongoing oversight [1, 2]. The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines likewise provide a widely used framework for evaluating the ethical acceptability of health-related research involving humans [3].

Within an academic medical institution, the maturity of research ethics governance cannot be represented by the existence of a committee alone. Written SOPs, clearly defined review pathways, protection of vulnerable participants, management of conflicts of interest, post-approval monitoring, investigator responsibilities and continuing ethics education are all relevant components of institutional capacity. Changes in these elements over time can therefore provide a documentary record of how an ethics-review system develops. A national assessment of research ethics committees in Myanmar has similarly examined organizational structure, membership and ethics training, review procedures, continuing review, resources and institutional commitment as important dimensions of REC functioning [4].

The Defence Services Medical Academy (DSMA) maintains an Ethical Review Committee (ERC), institutional SOPs for ethical review, and a continuing programme of responsible conduct of research (RCR) and research-ethics education. The 2024 third-edition SOP documents an institutional edition sequence of first edition in 2017, second edition in 2022 and third edition in 2024 [5]. An archived SOP 2017 was also available for detailed content analysis [6]. This study aimed to describe the longitudinal evolution of research ethics governance and RCR capacity building at DSMA through systematic documentary analysis of available SOPs and workshop programmes, with particular attention to governance, review processes, participant protection, investigator guidance, post-approval oversight, data governance and research-integrity education.

# 2. Materials and Methods

## 2.1. Study Design

This study used a retrospective descriptive documentary-analysis design. Documentary analysis is suitable for reconstructing institutional processes and changes over time when primary administrative and educational records are available [7].

## 2.2. Documentary Sources

Primary institutional sources comprised the DSMA ERC SOP labelled 2017 [6]; the 2022 institutional ERC SOP [8]; the 2022 SOP for Principal Investigators [9]; the 2024 Third Edition ERC SOP [5]; and available RCR/research-ethics workshop programmes from 2018, 2022, 2023, 2024 and 2026 [10-14]. The documents were treated as evidence of stated institutional policy, procedure and educational activity. They were not assumed to demonstrate implementation or effectiveness unless the documents themselves provided such evidence.

## 2.3. Data Extraction and Analytical Domains

A structured comparison framework was used to extract: edition/year; stated objective; ERC functions and composition; membership and quorum; independent consultation; review pathways; decision-making and communication; participant protection; vulnerable populations; informed consent; protocol amendments; continuing review and monitoring; archiving; investigator-facing guidance; research-type-specific guidance; data/material governance; conflict-of-interest documentation; annual/final reporting; and RCR workshop content. Documentary changes were categorized as continuity, clarification, formalization, differentiation, or expansion.

## 2.4. Interpretation of Documentary Change

An addition to a later SOP was interpreted only as evidence that the topic became explicitly documented in that edition. Absence from an earlier document was not interpreted as evidence that the practice did not occur. Similarly, repeated workshops were treated as evidence of recurring capacity-building activities, not as proof of improved knowledge, behavior, protocol quality or participant outcomes.

## 2.5. Ethical Considerations

The analysis uses institutional SOPs and workshop pro-

grammes and contains no participant-level research data. Institutional permission was obtained to access and analyze the documents included in the study. Formal ethical review was not required because the study was limited to documentary analysis and involved no identifiable personal or participant-level data.

# 3. Results

## 3.1. Documentary Chronology and SOP Development

The documentary record demonstrates successive stages of formal research-ethics governance. The 2024 third-edition SOP records the institutional edition sequence as 2017, 2022 and 2024 [5]. The archived 2017 SOP copy provides detailed evidence of the early governance framework, including ERC objectives and functions, committee composition and membership, quorum, protection of vulnerable participants, application and documentation requirements, review procedures, informed consent, expedited review, decision-making, follow-up and monitoring, archiving and member updating [6]. Together, these records support a longitudinal analysis of increasing procedural differentiation and formalization.

## 3.2. Governance and Committee Structure

The 2017 SOP described a multidisciplinary and multisectoral committee, a three-year membership duration, confidentiality obligations, declaration of conflicts of interest and a minimum quorum of five [6]. The 2022 institutional SOP retained this overall structure and explicitly included a second vice-chairperson identified as an independent person [8]. In the 2024 third edition, the quorum was more specifically articulated to include research-ethics expertise, a clinician, a biomedical scientist, community/non-governmental or legal representation, and a medical statistician [5]. These changes indicate increasing specificity in the documented composition of deliberative expertise.

## 3.3. Review Procedures and Decision-Making

Across the SOP series, ethical review included advance circulation of proposals, primary review, committee discussion, access to independent consultants, recorded decisions and written communication to investigators. The 2024 SOP retained expedited review for specified minimal-risk activities and described categories including use of existing clinical materials, recordings, surveys, interviews, focus groups, programme evaluation and related methodologies, subject to stated limitations [5]. Conflict-of-interest management was operationalized by requiring an affected member to withdraw from the relevant decision procedure [5].

## 3.4. Participant Protection and Informed Consent

Protection of research participants was a sustained feature across the documentary series. The 2017 SOP addressed vulnerable participants, children and adolescents, students and employees, medically vulnerable people, pregnant or nursing women, confidentiality, informed consent and emergency consent [6]. The 2022 PI-oriented SOP preserved these protections while providing investigator-facing guidance and templates for clinical studies, child research, health-system research, biological samples, educational research and genetic research [9]. The 2024 edition reorganized vulnerable-participant guidance into a dedicated chapter and informed consent into a separate chapter, including a specific procedure for requesting waiver of informed consent [5].

## 3.5. Differentiation of Research-Specific Guidance

A notable documentary development was the increasing differentiation of ethical guidance according to research design. The 2022 documents explicitly incorporated medical-education research and genetic research [8, 9]. The 2024 third edition further identified considerations for survey-based research, records-based research and genetic research and added a qualitative-research consent form [5]. This suggests an expansion from predominantly biomedical and clinical framing toward a broader range of research methodologies undertaken within an academic health institution.

## 3.6. Data, Materials and Conflict-of-Interest Governance

The 2024 appendices demonstrate further formalization of governance beyond protocol approval. They include a Material Transfer Agreement, a Data Ownership/Transfer/Use Agreement and a Conflict of Interest Declaration Form [5]. These documents provide explicit mechanisms for issues that extend across research conduct, data stewardship, material sharing and transparency of investigator interests.

## 3.7. Post-Approval Oversight and Reporting

Follow-up and monitoring were already present in earlier SOPs. The 2022 PI SOP required periodic reports no less frequently than annually, final reports, reporting of protocol deviations, renewed approval for amendments, communication of new risk information, notification of premature termination and changes of investigators or sites [9]. The 2024 edition retained continuing oversight and included standardized annual and final report forms, including fields for enrolment, adverse or unanticipated events, complaints and data storage [5]. The

documentary trajectory therefore shows increasing standardization of post-approval reporting.

### 3.8. Evolution of RCR and Research-Ethics Capacity Building

The educational record complements the SOP trajectory. The 2018 two-day RCR and research-ethics workshop covered research-ethics principles, integrity and misconduct, good laboratory practice, data ownership and sharing, ERC operational aspects, mentoring, conflict of interest, research monitoring, authorship and plagiarism, with group work and presentations [10]. In 2022, the RCR workshop addressed ethical considerations in human research and researcher responsibility with group work [12]. The 2023 programme included informed consent, data ownership and sharing, researcher responsibility and facilitated group presentations [13].

The 2024 workshop explicitly stated objectives to strengthen RCR and research-ethics capacity among DSMA faculty, promote awareness of human-research ethics, cultivate a research culture emphasizing integrity and prevent research misconduct [11]. Its sessions included human-research ethics, informed consent, data ethics, plagiarism, research misconduct and an overview of RCR, again incorporating group work and discussion [11]. The 2026 programme continued this pattern with RCR, informed consent, data ethics, ethical considerations in human research, research misconduct and group work [14].

Taken together, the workshop records demonstrate recurring institutional attention to both participant-protection ethics and broader responsible research conduct. The repeated use of discussion, group work and presentation suggest a sustained participatory educational format, although learning outcomes were not available for this documentary analysis.

***Table 1.*** *Selected milestones in the documentary evolution of DSMA research ethics governance.*

| Year | Documentary source | Selected developments | Interpretive significance |
|---|---|---|---|
| 2017 | ERC SOP | Broad governance framework; vulnerable participants; consent; expedited review; monitoring; archiving | Established comprehensive written operational framework in the available archive |
| 2018 | RCR & research-ethics workshop | Integrity, misconduct, GLP, data sharing, ERC operations, monitoring, authorship/plagiarism | Early documented comprehensive RCR capacity building |
| 2022 | Institutional ERC SOP | Independent vice-chairperson; medical-education and genetic-research guidance; operational forms | Greater differentiation of governance and research-specific guidance |
| 2022 | PI SOP | Investigator-facing procedures and multiple consent templates | Separation of investigator guidance from committee governance |
| 2022-2023 | RCR workshops | Human-research ethics, researcher responsibility, consent, data ownership/sharing | Continuity of ERC-led capacity building |
| 2024 | Third-edition ERC SOP | Thematic chapters; survey/records/qualitative/genetic research; consent waiver; MTA; data-use agreement; COI form; annual/final reports | Broader and more formalized governance architecture |
| 2024 | RCR workshop | Explicit objectives for integrity culture, misconduct prevention and faculty capacity | Capacity building linked explicitly to institutional research culture |
| 2026 | RCR workshop | RCR, consent, data ethics, human-research ethics, misconduct, group work | Continued ethics and integrity education |

***Table 2.*** *Major domains of SOP evolution.*

| Domain | 2017 available SOP | 2022 documents | 2024 third edition |
|---|---|---|---|
| Governance | Committee functions, composition, membership, quorum | Independent vice-chairperson explicitly identified | Quorum expertise specified in greater detail |

| Domain | 2017 available SOP | 2022 documents | 2024 third edition |
|---|---|---|---|
| Research types | Broad biomedical/human-participant framework | Medical-education and genetic research explicitly added | Survey, records-based, qualitative and genetic considerations explicitly organized |
| Investigator guidance | Integrated within main SOP | Separate PI SOP | Expanded forms and agreements within structured chapters/appendices |
| Consent | General, emergency and population-specific guidance | Multiple research-specific consent templates | Dedicated consent chapter; waiver request; assent and qualitative-research templates |
| Data/material governance | Data/confidentiality provisions | Data-related investigator considerations | MTA; data ownership/transfer/use agreement |
| Conflict of interest | Member declaration | Retained | Specific investigator COI declaration form |
| Post-approval oversight | Follow-up, monitoring, archiving | Annual/final reporting and amendment/deviation requirements | Standardized annual and final report forms |

## 4. Discussion

This documentary analysis suggests that research ethics governance at DSMA evolved through two interconnected processes: progressive formalization of written ERC procedures and recurring institutional investment in RCR education. The most important finding is not simply that later SOPs are longer, but that the documentary architecture became more differentiated. Governance provisions, investigator guidance, research-design-specific considerations, consent procedures, data/material agreements, conflict-of-interest documentation and post-approval reporting became increasingly explicit.

The trajectory is broadly consistent with a systems approach to research ethics. WHO operational guidance emphasizes that effective ethics review depends not only on committee review but also on appropriate composition, independence, training, transparent written procedures, record keeping and researcher responsibilities [1]. The DSMA documents contain elements across these domains, although this study was not designed as a formal compliance audit against WHO standards. The current Declaration of Helsinki also emphasizes ethical principles for medical research involving human participants and provides an important international reference point for institutional review systems [15].

A second important finding is the development of investigator-facing support. The separate 2022 PI SOP is noteworthy because it translates committee expectations into practical guidance for researchers. By 2024, the inclusion of specific considerations for survey, records-based, qualitative and genetic research further acknowledged methodological diversity. This is relevant in an academic medical institution where research may extend beyond clinical intervention studies into education, health systems, behavioral inquiry and secondary data analysis.

Third, the documentary record demonstrates increasing attention to research governance after initial approval. Annual reporting, final reporting, protocol amendments, deviations, adverse or unanticipated events, data storage and continuing review reflect a shift from ethics review as a single approval event toward longitudinal oversight. International guidance similarly conceptualizes ethics review as an ongoing responsibility rather than a one-time administrative decision [1, 3].

The RCR workshop series adds an educational dimension that cannot be inferred from SOPs alone. From 2018 through 2026, recurring programmes addressed integrity, misconduct, informed consent, data ethics, authorship/plagiarism, researcher responsibility and monitoring. The 2024 programme is especially informative because it explicitly links training to building RCR capacity, cultivating an integrity-oriented research culture and preventing misconduct. The recurrence of interactive group work suggests that capacity building was not limited to passive information delivery.

These findings should nevertheless be interpreted conservatively. Documentary expansion does not itself establish improved ethical quality, faster review, better investigator behavior or stronger participant protection. The next stage of institutional evaluation should therefore connect written governance with measurable implementation. Potential indicators include annual protocol volume, review turnaround time, proportions requiring major modification, frequency of expedited review, protocol deviations, continuing-review compliance, completeness of final reports, investigator training participation and pre/post-training knowledge or competency measures.

### 4.1. A Proposed Developmental Model

Based on the available documents, the evolution can provisionally be understood in four overlapping phases: (1) foundational written governance, represented by the early SOP framework; (2) differentiation and investigator orientation, represented by the 2022 institutional and PI documents; (3) expanded governance and standardization, represented by the 2024 third edition; and (4) sustained capacity building, represented by recurring RCR workshops across 2018-2026. These phases are analytical categories rather than formally designated institutional periods and should be revised if additional historical records become available.

### 4.2. Strengths and Limitations

A major strength of this study is its use of primary institutional documents spanning multiple years and representing both governance and educational activity. Combining SOPs with workshop programmes permits examination of the institutional ethics system through complementary operational and capacity-building lenses, rather than relying on retrospective recollection alone.

Several limitations should be considered. First, although the 2024 SOP documents the formal edition sequence as 2017, 2022 and 2024, the complete original 2017 and 2022 editions were not separately available in the reviewed set; an archived 2017 SOP copy was used to characterize the early framework. Second, SOP content represents stated institutional policy and cannot by itself establish implementation fidelity or effectiveness. Third, workshop programmes document intended educational content but do not provide complete attendance, competency, behavior-change or research-quality outcomes. Fourth, longitudinal protocol-review statistics were not available for the present analysis. Finally, undocumented interim revisions or local operational practices may not be represented in the documentary archive.

## 5. Conclusions

The available documentary record indicates that research ethics governance at DSMA has developed from a broad written framework for committee review into a more differentiated system incorporating investigator-specific guidance, research-design-specific considerations, structured consent procedures, data and material governance, conflict-of-interest documentation and standardized post-approval reporting. In parallel, recurring RCR workshops from 2018 through 2026 demonstrate sustained institutional attention to research ethics, integrity and researcher responsibility.

The significance of this evolution lies not in the number of SOP pages or workshops alone, but in the progressive articulation of an institutional system linking ethical review, investigator responsibilities, continuing oversight and capacity building. Future work should evaluate implementation and outcomes using prospective performance indicators and should examine how documented governance translates into the quality, timeliness and ethical conduct of research.

## Abbreviations

| | |
|---|---|
| CIOMS | Council for International Organizations of Medical Sciences |
| DSMA | Defence Services Medical Academy |
| ERC | Ethical Review Committee |
| MTA | Material Transfer Agreement |
| PI | Principal Investigator |
| RCR | Responsible Conduct of Research |
| SOP | Standard Operating Procedure |
| WHO | World Health Organization |

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## Author Contributions

**Ye Phyo Aung:** Conceptualization, Data curation, Formal Analysis, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing

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**Zaw Myint:** Data curation, Formal Analysis, Methodology, Visualization, Writing – original draft

**Mo Mo Than:** Conceptualization, Methodology, Supervision, Validation, Writing – review & editing

## Data Availability Statement

The documentary data consist of institutional DSMA ERC SOPs and RCR/research-ethics workshop programmes. Availability to external readers is subject to institutional permission.

## Conflicts of Interest

The authors declare no conflicts of interest.

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## Biography

**Ye Phyo Aung** is a senior lecturer and head at Defence Services Medical Academy, Department of Medical Education, Yangon, Myanmar. He acquired his M. H. P. E in Medical Education from Maastricht University in 2017, and his fellowship from the International Association of Medical Science Educators in 2023. He participated as a reviewer in Medical Science Educator (MSE), The Asia Pacific Scholar (TAPS), and Medical Education (online) since 2021. He has participated in an international research collaboration in the medical education field in recent years. He currently serves as Secretary, Chair, Speaker, and Judge at national and international conferences.

**Myo Zaw Thu** is an Assistant Lecturer in the Department of Forensic Medicine at the Defence Services Medical Academy, Myanmar. He received his MBBS degree in 2006, MMedSc (Medical Jurisprudence) in 2013, Doctorate of Medical Science (Medical Jurisprudence) in 2023, and Diploma in Medical Education in 2025. He actively contributes to undergraduate and postgraduate medical education. His research interests include forensic science, medical ethics, and medical education.

**Aung Thu** is currently working as an assistant Lecturer at the Department of Forensic Medicine, Defence Services Medical Academy. He received MBBS in 2006, MMedSc (Medical Jurisprudence) in 2013 and a Diploma in Medical Education in 2019.

**Thant Zin** obtained his MBBS degree in 2006 from the Defence Services Medical Academy (DSMA). Furthering his specialization, he completed M. Med. Sc. (Medical Jurisprudence) at DSMA in 2011, followed by an M. Sc. (Forensic Science) from Mahidol University, Thailand, in 2017. He then earned a Diploma in Medical Education (Dip. Med. Ed) from DSMA in 2018 and achieved his Dr. Med. Sc. (Medical Jurisprudence), from DSMA in 2026. Currently, he serves as an Assistant Lecturer in the Department of Forensic Medicine at DSMA and functions as a secretary member of the Ethical Review Committee (DSMA).

**Zin Min Htike** is an assistant lecturer in medical education department for about six years and then transfer to medicine department as an assistant lecturer for about one year. He also serves as a general physician at No 1/1000 bedded Defense Services General Hospital. He is a good medical educator as a facilitator in Workshop module (previously in Teaching/Learning Strategy module). He actively participates in Medical Education Committee now. He has been experiencing medical education for more than five years.

**Zaw Myint** is a senior lecturer in the Department of Anatomy at the Defence Services Medical Academy. He received an MBBS in 2003, an M. Med. Sc (Anatomy) in 2011, a Diploma in Medical Education in 2015, and a Doctor of Philosophy (Ph. D.) in Anatomy in 2020. At DSMA, he actively contributes through academic and administrative appointments: Module Coordinator (2024–Present) and Medical Year 1 Coordinator (2021–2023). He serves as an active committee member, contributing to the development and oversight of advanced degree tracks: Master of Medical Sciences (M. Med. Sc) in Anatomy Program, Doctor of Philosophy (Ph. D.) in Anatomy Program.

**Mo Mo Than** is a Professor and Head of the Department of Biochemistry at Defence Services Medical Academy (DSMA), Myanmar. She graduated MBBS degree in 1995. She obtained a PG Diploma in Biotechnology (1998), MMedSc (Biochemistry) (2000) & Diploma in Medical Education (2007). Then she earned PhD (Biochemistry) in 2011. She's devoted to research, particularly in Molecular Genetics, Clinical Biochemistry, Endocrinology, Medical Education, and population genetics. She received training in research ethics from the University of Maryland, Baltimore, USA, in 2015, and became a FAIMER fellow (FFRI) in 2022. She's won accolades for her work and produced multiple publications both locally and internationally.

## Research Field

**Ye Phyo Aung:** Medical and Health Sciences, Medical Education, Clinical Research
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