

# Ethics, Regulation, and Governance in Dual-Use Research: A Systematic Review

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DOI: <https://dx.doi.org/10.47772/IJRISS.2025.90400027>

Received: 19 March 2025; Accepted: 25 March 2025; Published: 26 April 2025

## ABSTRACT

This systematic review explores dual-use research challenges, synthesizing insights on ethical, regulatory, and governance aspects. Dual-use research, with its potential for both beneficial and harmful applications, demands careful examination to balance innovation and public safety. This review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology, analyzing 28 articles sourced from Web of Science (WOS), Scopus, PubMed, and Sage databases. The analysis identifies three themes: (1) Ethics and philosophical perspectives, (2) Regulatory frameworks and export control mechanisms, and (3) Technological applications and governance approaches. The findings emphasize the critical need for ethical education, collaborative governance, and adaptive regulatory frameworks to address dual-use risks. Key challenges include inconsistent regulatory definitions, fragmented implementation, and gaps in international cooperation. By integrating ethical considerations into research practices and aligning regulatory efforts globally, the study highlights pathways to enhance governance and reduce misuse risks. This review provides actionable insights for policymakers, researchers, and institutions, advancing the discourse on responsibly managing dual-use innovations.

**Keywords:** Biosecurity, biotechnology, dual-use research, ethics, research ethics

## INTRODUCTION

Scientific advancements in fields like biotechnology, artificial intelligence, and data science present immense benefits while raising significant ethical challenges, particularly concerning "dual-use research of concern" (DURC). This refers to research that, while intended to benefit society, may also be misused for harmful purposes, such as bioterrorism or cyber threats [2]. Awareness of such risks surged after the 2001 anthrax attacks, sparking discussions about biosecurity and the ethical responsibilities of researchers [3]. Researchers often face difficult decisions about whether pursuing knowledge could inadvertently create risks, such as the misuse of their findings, highlighting the tension between progress and safety [4]. Technologies like CRISPR-Cas9 and artificial intelligence have enabled breakthroughs in medicine and surveillance but have simultaneously heightened concerns about misuse of harmful applications [5-7].

Governance of dual-use research is further complicated by varying regulatory frameworks. For example, while the Biological Weapons Convention (BWC) addresses biosecurity issues, its lack of enforcement mechanisms leaves significant gaps [8, 9]. Despite ethical guidelines and risk assessments being introduced, their inconsistent application underscores the need for robust oversight [2, 9]. Addressing these challenges requires an integrated framework of international cooperation [10-12], ethical education [13-15], robust oversight [13-15] and adaptable policies to ensure that scientific advancements do not inadvertently cause harm [15, 16].

## BACKGROUND OF STUDY

Dual-use research refers to scientific studies that have the potential for both positive advancements and

unintended harmful consequences. The U.S. National Science Advisory Board for Biosecurity (NSABB) defines "dual-use research of concern" (DURC) as research that is reasonably expected to produce knowledge or technologies that could be misapplied, posing risks to public health, safety, or environmental security [17, 18]. This inherent duality raises ethical challenges, particularly regarding the responsibilities of researchers and institutions in managing potential risks.

Fundamental ethical principles, including beneficence, non-maleficence, and justice, compel researchers to carefully weigh the benefits of scientific discovery against the risks of potential misuse. While breakthroughs in public health can lead to life-saving treatments, they may also unintentionally provide pathways for the creation of biological threats. The principle of justice underscores the need for fair distribution of both risks and benefits, ensuring that no group bears a disproportionate burden. Furthermore, maintaining a balance between academic freedom and societal responsibility remains a critical concern, as unrestricted access to research findings could inadvertently enable malicious applications [19]. Research Ethics Committees (RECs) are instrumental in navigating these ethical complexities, but additional oversight mechanisms are needed to reinforce accountability and align scientific advancements with broader societal interests [15, 20, 21].

Historical cases of bioterrorism and accidental pathogen releases have underscored the risks associated with dual-use research, exposing regulatory gaps and prompting stronger calls for oversight to prevent misuse. For instance, concerns over laboratory-engineered viruses, such as the controversies surrounding gain-of-function research, have sparked debates about the adequacy of current governance structures. Despite efforts to strengthen regulations, rapid advancements in biotechnology and genetic engineering continue to outpace existing frameworks, reinforcing the need for robust ethical safeguards [22, 23]. Dual-use dilemmas offer valuable insights into the challenges of balancing scientific progress with security concerns, highlighting the need for shared responsibility among researchers, institutions, and policymakers [24, 25].

## Challenges in Academia

Several incidents illustrate the challenges of dual-use research within academic institutions. For example, Indiana University exported genetically modified fruit flies containing a ricin toxin gene without the required licenses between 2017 and 2021. Although intended for research, these exports violated U.S. Export Administration Regulations (EAR), highlighting the need for rigorous compliance measures to prevent misuse [26]. Similarly, a Florida University case revealed fraudulent procurement of biochemicals worth \$4.9 million, diverted to unauthorized destinations through falsified export documents. This incident underscores the importance of institutional vigilance and ethical responsibility [27]. These cases reflect a broader pattern of lapses in export control compliance, as seen in instances involving unauthorized exports of biological materials and technology leaks by academic institutions globally [28, 29]. The delicate balance between academic freedom, international collaboration, and national security requires robust compliance frameworks to mitigate dual-use risks effectively.

## MATERIAL AND METHODS

Table I The Search Strings

Source	Strings
Web of Science	(( "approach" OR "rule*" OR "legal" OR "ethic*" OR "research ethic*" OR "conduct*" OR "philosoph*" OR "moral obligation*" OR "responsible*" OR "biotech*" OR "biosecurit*" OR "guideline*" OR "principle*" OR "integrit*" OR "compliance*" OR "regulation*" OR "bioethic*" OR "biodefen*e*" OR "biosafet*" ) AND ( "dual use" )) (Title) and 2024 or 2023 or 2022 or 2021 or 2020 (Publication Years) and Article (Document Types) and English (Languages)
Scopus	TITLE ( ( ( "approach" OR "rule*" OR "legal" OR "ethic*" OR "research ethic*" OR "conduct*" OR "philosoph*" OR "moral obligation*" OR "responsible*" OR "biotech*" OR "biosecurit*" OR "guideline*" OR "principle*" OR "integrit*" OR "compliance*" OR "regulation*" OR "bioethic*" OR "biodefen*e*" OR "biosafet*" ) AND ( "dual use" ) ) ) AND ( LIMIT-TO ( PUBYEAR , 2020 ) OR

	LIMIT-TO ( PUBYEAR , 2021 ) OR LIMIT-TO ( PUBYEAR , 2022 ) OR LIMIT-TO ( PUBYEAR , 2023 ) OR LIMIT-TO ( PUBYEAR , 2024 ) ) AND ( LIMIT-TO ( DOCTYPE , "ar" ) ) AND ( LIMIT-TO ( LANGUAGE , "English" ) )
Sage	(( "approach" OR "rule*" OR "legal" OR "ethic*" OR "research ethic*" OR "conduct*" OR "philosoph*" OR "moral obligation*" OR "responsible*" OR "biotech*" OR "biosecurit*" OR "guideline*" OR "principle*" OR "integrit*" OR "compliance*" OR "regulation*" OR "bioethic*" OR "biodefen*e*" OR "biosafet*" ) AND ( "dual use" )) Applied Filters 2019 – 2024, Article type: Research article
PubMed	(( "approach"[Title] OR "rule*" [Title] OR "legal"[Title] OR "ethic*" [Title] OR "research ethic*" [Title] OR "conduct*" [Title] OR "philosoph*" [Title] OR "moral obligation*" [Title] OR "responsible*" [Title] OR "biotech*" [Title] OR "biosecurit*" [Title] OR "guideline*" [Title] OR "principle*" [Title] OR "integrit*" [Title] OR "compliance*" [Title] OR "regulation*" [Title] OR "bioethic*" [Title] OR "biodefen*e*" [Title] OR "biosafet*" [Title]) AND ( "dual use" [Title])) Filters applied: in the last 5 years, English

Table II The Selection Criterion In Searching

Criterion	Inclusion	Exclusion
Language	English	Non-English
Timeline	2019 – 2024	< 2019
Literature type	Journal (Article)	Conference, Book, Book chapter, Review
Publication Stage	Final	In Press

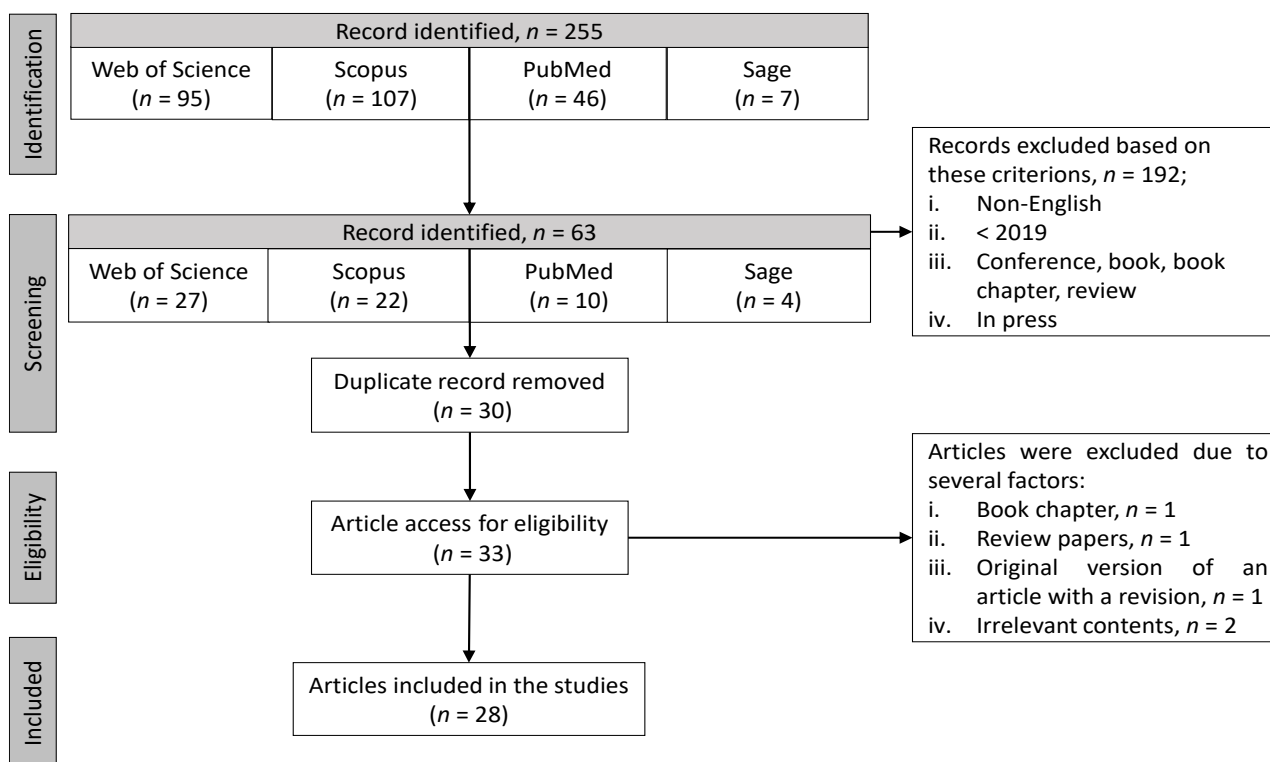


Fig. 1 Flow diagram of the proposed searching study – PRISMA [1]

## Identification

The systematic review methodology consisted of three primary stages aimed at identifying a significant number of pertinent papers for this study. Initially, keywords and associated terms were pinpointed through consultations with dictionaries and existing literature. Subsequently, relevant phrases were employed to formulate search strings for databases including Web of Science (WOS), Scopus, PubMed and Sage (refer to Table 1). In the initial phase of the systematic review process, a total of 255 articles were effectively retrieved from these databases. All databases were last assessed in December 2024.

## Screening

During the second phase, we excluded 192 articles based on the exclusion and inclusion criteria as outlined in Table 2. Next step was to remove duplicated papers. At this phase, 30 articles were excluded.

## Eligibility

In the third phase, referred to as the eligibility assessment, we compiled a total of 33 articles. At this stage, we conducted a thorough review of the titles and essential content to ensure alignment with the inclusion criteria and relevance to the research objectives. Three articles were excluded during this process: one was the original version of an article that had a corrected version published, one was a review paper, and one was a book chapter. Additionally, two articles were excluded due to irrelevant content. Consequently, 28 articles were retained for further analysis (refer to Figure 1 for details).

## Data Abstraction and Analysis

The PRISMA flow diagram illustrated in Figure 1 outlines the systematic approach employed in identifying, screening, and selecting articles for this review. Temporal trends in dual-use research publications are shown in Figure 2, which highlights an increase in research output from 2019 to 2024, with significant contributions in recent years. The distribution of articles across journals is depicted in Figure 3, showcasing the diverse range of sources contributing to the field, with notable representation from Research Ethics and Global Trade and Customs Journal.

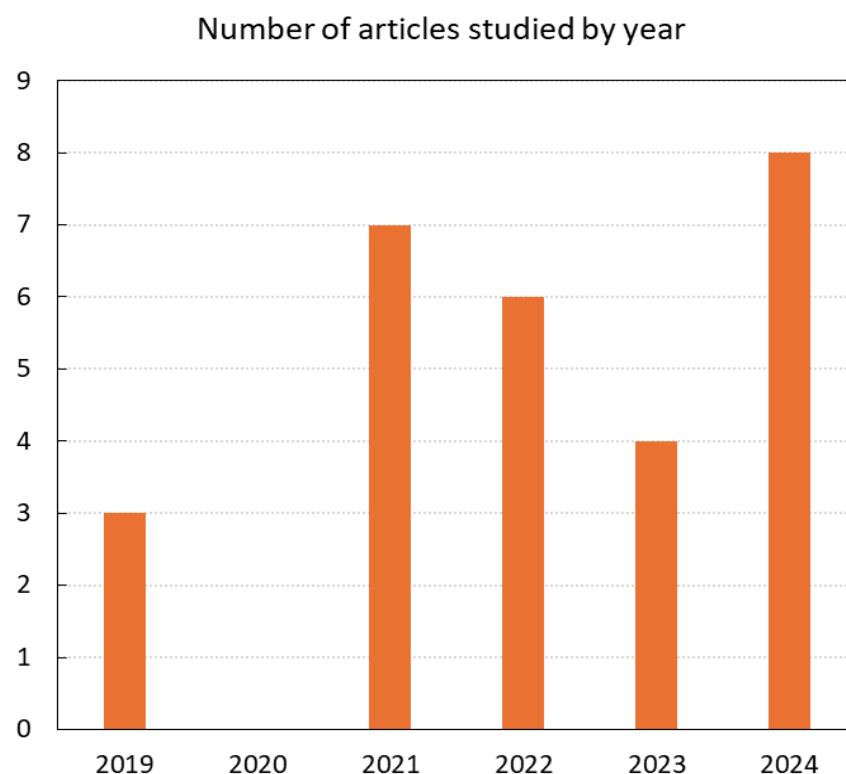


Fig. 2 Year of publications the studied articles

## RESULTS AND FINDINGS

To conduct a systematic literature review following the PRISMA guidelines, categorizing articles into themes is essential. Based on the titles of articles studied, three primary themes were identified, providing a structured framework for analysis. It is worth noting that this classification is based on titles alone, and further review of full texts is needed for a comprehensive understanding. As illustrated in Figure 4, the articles are grouped into three themes. Theme 1, representing 28% of the articles, focuses on ethics and philosophical perspectives, addressing researchers' responsibilities, moral frameworks, and philosophical debates surrounding dual-use

dilemmas. Theme 2, comprising 36% of the articles, emphasizes regulatory frameworks and export control mechanisms, highlighting international policies, export controls, and sanctions aimed at balancing scientific progress with security and human rights. Theme 3, making up 36% of the articles, explores technological applications and governance, emphasizing innovations in biotechnology, material sciences, and biosecurity, alongside governance strategies to mitigate misuse risks.

### **Ethics and philosophical perspectives on dual-use research**

This theme explores the ethical dilemmas, philosophical considerations, and responsibilities surrounding dual-use research. The division of responsibilities in addressing dual-use risks is a central debate. While scientists are often viewed as key actors, the limitations of precautionary principles and biases in risk-benefit analyses highlight the need for shared responsibility with external agents for comprehensive oversight [9]. This aligns with the argument that educating scientists about ethics and professional responsibility, as seen through frameworks like Geoffrey Vickers' Appreciative System, can integrate dual-use concerns into scientific practice and strengthen international treaties against misuse [30].

Germany's approach focuses on letting researchers regulate themselves and raising awareness to balance scientific freedom with security concerns. The German Joint Committee's framework, including key questions for researchers, demonstrates a practicable method for handling security-relevant research while fostering a culture of responsibility [13]. Complementing this, reflections on philosophical research show that misuse of theories, while rare, can occur under specific social conditions. Scholars are encouraged to make their arguments conclusive, engage in public philosophy, and emphasize the intended purpose of their theories to minimize misuse [31].

Empirical studies in emerging medical biotechnology further reveal varying perspectives among scientists regarding dual-use risks. While many support self-regulation and external oversight, misunderstandings about ethics and regulations persist, highlighting the need for stronger national mechanisms and enhanced ethical awareness to ensure responsible innovation [32].

Responsible Research and Innovation (RRI) frameworks offer another pathway to addressing dual-use concerns. Moving beyond legal compliance, RRI integrates anticipation, reflection, engagement, and action into a nonlinear, experimental approach that fosters learning and dialogue, as demonstrated in the Human Brain Project [33]. Balancing regulation and scientific autonomy are crucial, as overly simplistic cost-benefit analyses may lead to excessive restrictions, whereas free speech theory and institutional design principles can help ensure balanced regulation [34].

The ethical comparison of slippery-slope arguments and dual-use problems, particularly in the context of CRISPR-Cas9 genome editing, underscores their differences. While slippery-slope arguments address risks of gradual ethical erosion, dual-use concerns focus on the immediate potential for both beneficial and harmful applications, contributing to a deeper understanding of the ethical challenges in biomedical research [35]. Therefore, addressing dual-use ethical challenges requires a combination of shared responsibility, ethical education, and innovative frameworks like RRI to guide researchers, policymakers, and institutions in mitigating risks while supporting responsible scientific progress.

### **Regulatory frameworks and export control mechanisms**

This theme explores the challenges in developing regulatory frameworks and export control mechanisms for dual-use items, focusing on their complexities and limitations. The lack of a universal definition for "dual-use items" complicates international control, as legal regimes use varied criteria like peaceful or non-peaceful uses and intentionality, leading to inconsistencies and undermining legal certainty [36].

The European Union's Regulation 2021/821 introduced important changes, such as expanded definitions, new export authorizations, and technical assistance provisions. These updates aim to enhance compliance, accountability, and human rights considerations, particularly for emerging technologies [37, 38]. However, challenges persist, as illustrated by cyber-surveillance items, whose misuse raises serious human rights

concerns. Incorporating human rights into export controls marks a significant shift but remains difficult to implement effectively in practice [39, 40].

China's evaluation of dual-use research in medical biotechnology highlights similar issues. Inconsistent risk assessments, inadequate review mechanisms, and limited expertise weaken oversight efforts, underscoring the need for a stronger governance framework to balance innovation with safety [41]. Likewise, Italy's experience shows how dynamic regulatory changes require research institutions and private entities to prioritize trade compliance to avoid breaches [42].

Fragmented implementation of dual-use sanctions across European Union (EU) Member States reveals structural challenges that hinder policy coherence. Variations in national licensing and rule interpretations complicate efforts to achieve a unified approach to dual-use controls [43]. Meanwhile, United States sanctions demonstrate geopolitical influence over global dual-use trade. By stigmatizing targeted states, United States sanctions indirectly reduce third-party exports, reflecting the strategic use of export controls to align international behavior with national priorities [44]. Shifts in United States and EU export controls further highlight the intersection of national security, economic goals, and human rights agendas. However, these goals often conflict, creating regulatory barriers that impact emerging technologies and global trade [45]. As a result, harmonizing regulatory frameworks, improving international cooperation, and addressing national-level inconsistencies are essential to ensuring effective governance of dual-use items. Balancing security, trade, and human rights remains a pressing challenge for policymakers worldwide.

### **Technological applications and governance approaches in dual-use research**

This theme highlights the technological advancements and governance strategies necessary for managing dual-use risks across scientific fields. Innovative materials and biotechnological applications demonstrate the dual-use potential for societal benefit while raising ethical and security challenges. For example, sustainable antimicrobial coatings enhance fruit preservation and environmental safety, showcasing practical applications in food technology with minimal ecological impact [46]. Similarly, the synthesis of high-nitrogen materials using electrocyclization introduces significant advancements in materials science, with potential applications in both civilian and defense sectors [47]. A multidimensional framework for understanding dual-use risks categorizes technologies based on their ethical, technical, and situational properties. This structured approach aids in evaluating and mitigating risks while promoting responsible innovation [48].

In public health, dual-use concerns extend to behavioral research, such as studies on alcohol and cannabis co-use among college students. Findings emphasize the need to address addictive behaviors with evidence-based interventions while managing societal risks [49]. Governance strategies play a critical role in mitigating dual-use risks. An incentive-based, multistakeholder approach to DNA screening proposes practical solutions to ensure biosafety and responsible access to potentially sensitive genetic materials [50]. Additionally, research on the dual-use of agro-industrial wastes for biofuel and enzyme production demonstrates cost-effective, sustainable processes, showcasing the dual benefits of waste valorization and renewable energy [51].

Educational initiatives for managing bio risk, such as active learning workshops in Egypt, address deficiencies in biosafety training and equip researchers with tools to responsibly manage hazardous biological materials. These initiatives demonstrate how hands-on education can reduce risks and promote sustainable bio risk management [52]. Ethics committees, as highlighted by the World Health Organization, offer valuable oversight for dual-use research by providing ethical guidance and fostering international coordination, though their role remains limited in many countries [53].

Innovative engagement strategies, such as comic-based approaches, offer creative methods for communicating dual-use research findings. These approaches can engage wider audiences, distill complex findings, and foster societal dialogue, though they require careful planning to avoid oversimplification [54]. Finally, experimentalist governance models propose a dynamic, four-stage approach to managing dual-use biotechnology risks, integrating local action, global consultation, and continuous evaluation to ensure effective governance [55].

### Distribution of selected journals for studied articles

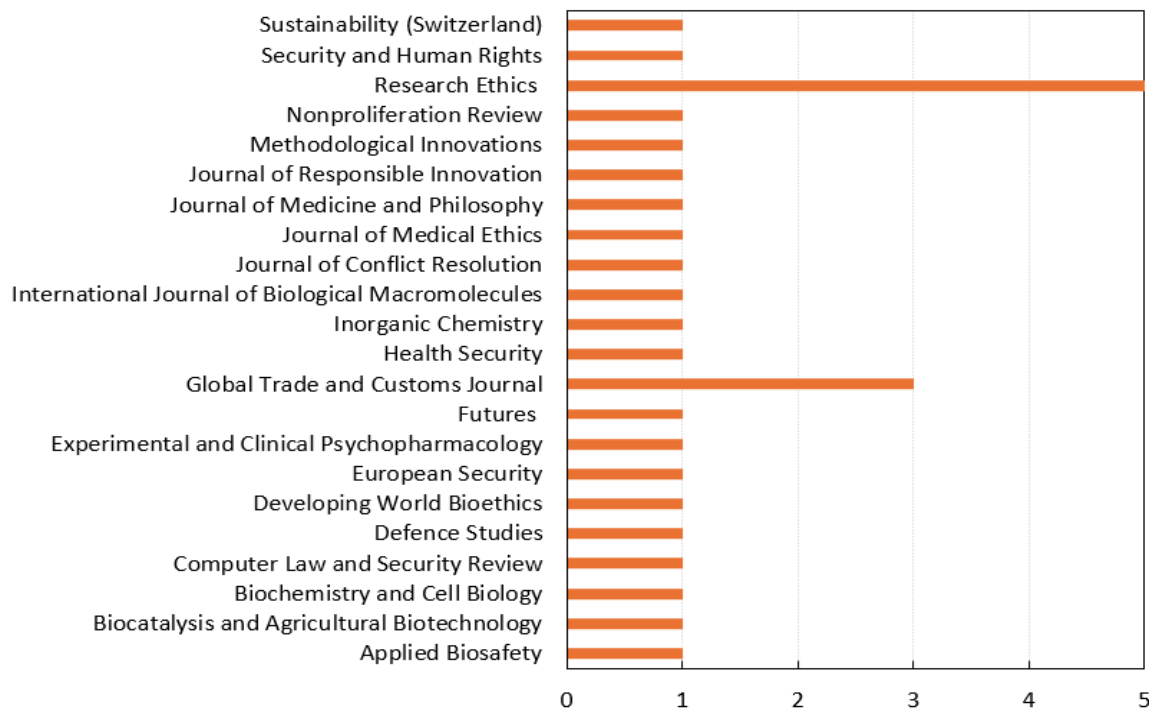


Fig. 3 Distribution of articles by journal sources for dual-use research

Hence, advancements in technology and governance highlight the importance of balancing innovation with safety. Collaborative governance frameworks, educational initiatives, and sustainable technological applications are essential for mitigating dual-use risks while ensuring scientific progress aligns with societal needs.

### Distribution of articles across the themes

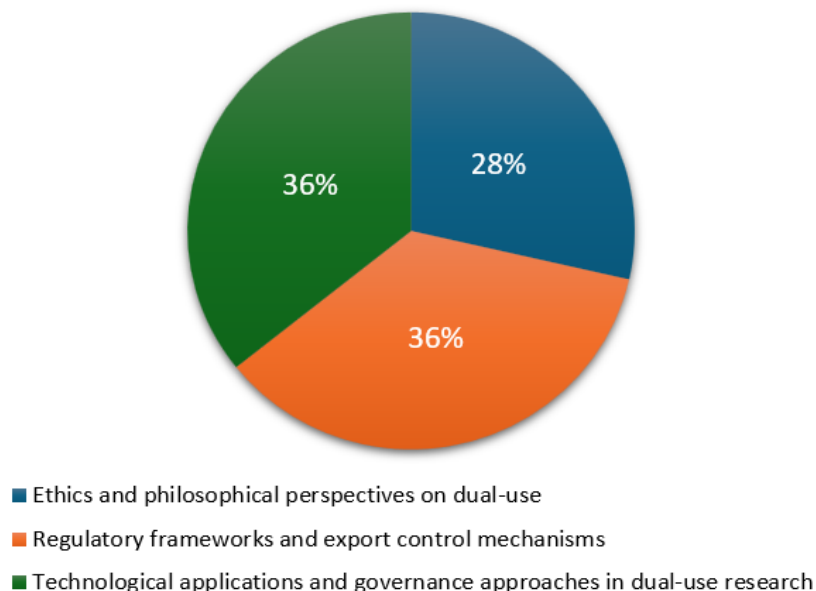


Fig. 4 Distribution of themes for the studied articles.

## DISCUSSIONS

The ethical dilemmas and philosophical considerations surrounding dual-use research emphasize the critical need for shared responsibility. Scientists, while central to innovation, cannot bear the sole burden of mitigating dual-use risks. Several studies highlight the role of external agents and collaborative frameworks in enhancing

ethical oversight, such as Germany's self-regulatory model, which fosters awareness and responsibility in security-sensitive research. The integration of ethical education, particularly through frameworks like Responsible Research and Innovation (RRI), underscores the importance of embedding societal values into research practices. Philosophical explorations of dual-use risks, including ethical debates on CRISPR-Cas9, reveal the need for researchers to make their arguments conclusive and to engage with public discourse to prevent misuse. Collectively, these findings reinforce the importance of balancing scientific autonomy with societal safeguards to address dual-use dilemmas effectively.

The regulatory landscape for dual-use research is marked by significant advancements, such as the European Union's Regulation 2021/821, which incorporates human rights considerations and addresses emerging technologies like cyber-surveillance. However, the review identifies persistent challenges, including inconsistent definitions of dual-use items, fragmented implementation across regions, and geopolitical influences. United States sanctions, for instance, demonstrate the strategic use of export controls to shape international trade, yet they also highlight the complexities of aligning national interests with global governance. China's evolving framework for dual-use medical biotechnology reveals additional gaps in assessment capabilities and institutional coherence. These findings underscore the need for harmonized international policies, improved risk assessment mechanisms, and collaborative efforts to address the complexities of dual-use trade.

Advances in materials science, biotechnology, and behavioral research illustrate the dual-use potential of emerging technologies. From antimicrobial coatings and high-nitrogen materials to biodiesel production and DNA screening, these innovations demonstrate the benefits of dual-use applications in addressing societal challenges. However, they also highlight the need for robust governance strategies to mitigate risks. Governance models such as incentive-based frameworks for DNA screening and experimentalist approaches to biotechnology governance emphasize the importance of multi-stakeholder engagement, dynamic regulations, and educational initiatives. Ethical and safety considerations remain central to ensuring that dual-use technologies are applied responsibly, aligning innovation with societal needs and global security priorities. Together, these themes highlight the intricate balance required to address dual-use research challenges. The review emphasizes that integrating ethical responsibility, adaptive regulations, and collaborative governance is essential for managing the risks associated with dual-use research while maximizing its societal benefits.

## CONCLUSIONS

In conclusion, this review highlights the diverse challenges and opportunities of dual-use research, emphasizing the need for a balanced approach. Ethical and philosophical considerations stress shared responsibility among researchers, institutions, and external agents to address dual-use risks. Frameworks like Responsible Research and Innovation (RRI) underscore the importance of embedding societal values into research practices while fostering public discourse to prevent misuse.

Regulatory advancements, such as the European Union's Regulation 2021/821, demonstrate progress in tackling dual-use concerns, yet challenges like inconsistent definitions, fragmented implementation, and geopolitical influences require harmonized international policies and improved risk assessments. The review also showcases the dual-use potential of emerging technologies in areas such as materials science, biotechnology, and behavioral research, underscoring their benefits in addressing societal needs. However, robust governance models, dynamic regulations, and ethical oversight remain crucial to mitigate risks and align these advancements with global security priorities.

This review highlights the importance of integrating ethical responsibility, adaptive regulatory frameworks, and collaborative governance to manage the complexities of dual-use research effectively. Such an approach ensures that scientific innovation contributes positively to societal progress while minimizing risks.

## ACKNOWLEDGMENT

This work is funded by the Universiti Teknologi Malaysia through Professional Development Research University [Q.K130000.21A2.07E01, 2023].

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