

Institutionalizing European Research Area Principles in Georgian Universities through Research Ethics Governance

ევროპული კვლევითი სივრცის პრინციპების ინსტიტუციონალიზაცია
საქართველოს უნივერსიტეტებში კვლევის ეთიკის მმართველობის მეშვეობით

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Abstract

Introduction: Research ethics is an important component of responsible research governance within the European Research Area (ERA). This study examines how, and to what extent, ERA-related expectations concerning ethical research are formally translated into research ethics governance in Georgian universities. **Methodology:** The study uses comparative qualitative document analysis of seven institutional instruments that regulate research ethics, including research ethics council or committee regulations, biomedical ethics regulations, research ethics standards, and related institutional ethics provisions. A Research Ethics Governance Assessment Framework is applied across five dimensions: normative ethical alignment; institutional responsibility and authority; governance positioning and independence; ethical review and procedural capacity; and accountability, transparency, and oversight. **Results:** The documents show broad convergence around participant dignity and autonomy, informed consent, confidentiality, risk assessment, researcher responsibility, impartial review, and protection of vulnerable participants. Greater variation concerns the organizational authority and independence of ethics bodies, continuing review and monitoring, committee training, quality assurance, reporting, and appeals. **Conclusions:** The selected Georgian universities demonstrate substantive but uneven institutionalization of research ethics governance. The findings concern only the research ethics arrangements evidenced in the analyzed documents and do not assess each university's wider research-integrity system, which may be governed through separate instruments.

Keywords: European Research Area, ethics; ethics governance, Georgia.

აბსტრაქტი

შესავალი: კვლევის ეთიკა პასუხისმგებლიანი კვლევითი მმართველობის მნიშვნელოვანი კომპონენტია ევროპული კვლევითი სივრცის (European Research Area, ERA) ფარგლებში. წინამდებარე კვლევა შეისწავლის, როგორ და რა ხარისხით აისახება ევროპულ კვლევით სივრცესთან დაკავშირებული ეთიკური კვლევის მოთხოვნები საქართველოს უნივერსიტეტებში კვლევის ეთიკის მმართველობის ფორმალურ მექანიზმებში. **მეთოდოლოგია:** კვლევა ეფუძნება შვიდი ინსტიტუციური დოკუმენტის შედარებით თვისებრივ ანალიზს. აღნიშნული



დოკუმენტები არეგულირებს კვლევის ეთიკის საკითხებს და მოიცავს კვლევის ეთიკის საბჭოებისა თუ კომიტეტების დებულებებს, ბიოსამედიცინო ეთიკის მარეგულირებელ დოკუმენტებს, კვლევის ეთიკის სტანდარტებსა და ეთიკასთან დაკავშირებულ სხვა ინსტიტუციურ ნორმებს. ანალიზისთვის გამოყენებულია კვლევის ეთიკის მმართველობის შეფასების ჩარჩო, რომელიც ხუთ განზომილებას მოიცავს: ეთიკურ ნორმებთან შესაბამისობა; ინსტიტუციური პასუხისმგებლობა და უფლებამოსილება; მმართველობით სტრუქტურაში ეთიკის ორგანოების ადგილი და დამოუკიდებლობა; ეთიკური შეფასებისა და პროცედურული განხორციელების შესაძლებლობები; ანგარიშვალდებულება, გამჭვირვალობა და ზედამხედველობა. **შედეგები:** დოკუმენტების ანალიზმა გამოავლინა ფართო თანხვედრა ისეთ ფუნდამენტურ ეთიკურ პრინციპებთან, როგორებიცაა კვლევის მონაწილეთა ღირსებისა და ავტონომიის პატივისცემა, ინფორმირებული თანხმობა, კონფიდენციალურობა, რისკების შეფასება, მკვლევრის პასუხისმგებლობა, მიუკერძოებელი ეთიკური შეფასება და მოწყვლადი მონაწილეების დაცვა. უფრო მნიშვნელოვანი განსხვავებები გამოვლინდა ეთიკის ორგანოების ორგანიზაციული უფლებამოსილებისა და დამოუკიდებლობის, მიმდინარე ეთიკური ზედამხედველობისა და მონიტორინგის, კომიტეტების წევრთა გადამზადების, ხარისხის უზრუნველყოფის, ანგარიშებისა და გასაჩივრების მექანიზმების მიმართულებით. **დასკვნები:** საქართველოს შერჩეულ უნივერსიტეტებში კვლევის ეთიკის მმართველობის ინსტიტუციონალიზაციის მნიშვნელოვანი, თუმცა არათანაბარი დონე ვლინდება. კვლევის შედეგები შემოიფარგლება მხოლოდ გაანალიზებულ დოკუმენტებში ასახული კვლევის ეთიკის მმართველობის მექანიზმებით და არ მოიცავს თითოეული უნივერსიტეტის აკადემიური და კვლევითი კეთილსინდისიერების უფრო ფართო სისტემის შეფასებას, რომელიც შესაძლოა ცალკეული ინსტიტუციური დოკუმენტებით რეგულირდებოდეს.

საკვანძო სიტყვები: ევროპული კვლევითი სივრცე; კვლევის ეთიკა; ეთიკის მმართველობა; საქართველო.

1. Introduction

The European Research Area (ERA) has developed from an initiative aimed at reducing fragmentation in European research into a broader framework for coordinating the values, conditions, and institutional environments within which research is conducted. The Pact for Research and Innovation in Europe identifies ethics and integrity of research and innovation among the common values underpinning the ERA and recommends that Member States apply these values within their research and innovation systems (Council of the European Union, 2021). Because the Pact is a Council Recommendation rather than a directly binding regulatory instrument prescribing a uniform university model, ERA-related principles are best treated in this study as a normative and policy framework for assessing institutional alignment and translation, not as a legal compliance checklist.

This distinction is particularly important for research ethics governance. European research policy establishes a strong expectation that research should be conducted responsibly and according to appropriate ethical standards, but it does not require every university to organize ethical review through an identical committee structure. Universities may establish institution-wide research ethics committees, faculty-level councils, biomedical ethics committees, or other arrangements suited to disciplinary and organizational contexts. The analytical question is therefore not whether an institution reproduces one prescribed European model, but whether ethical principles are translated into credible institutional arrangements for reviewing and overseeing research.

Research ethics governance is understood here in a deliberately focused sense. It concerns the institutional arrangements used to assess the ethical acceptability of research, particularly research involving human participants or other ethically sensitive activities. Relevant elements include participant dignity and autonomy, informed consent, privacy and confidentiality, risk-benefit assessment, protection of vulnerable participants, conflicts of interest in ethical review, the authority and independence of ethics bodies, prospective review, continuing oversight, documentation, appeals, and accountability.

This article does not evaluate the broader research-integrity systems of the selected universities. Research integrity may encompass matters such as fabrication and falsification, plagiarism, authorship, publication practices, data stewardship, supervision, and procedures for investigating misconduct. Universities may regulate these issues in separate codes, policies, disciplinary rules, or research-management instruments that are not part of the documentary corpus analyzed here. The absence of such provisions from a research ethics committee regulation therefore cannot be interpreted as evidence that the university lacks research-integrity governance.

Georgia provides a useful setting for examining the institutional translation of European research ethics principles. Georgian universities increasingly participate in European higher education and research structures, while institutional attention to research quality, internationalization, ethical review, and accountability has expanded. At the same time, universities have developed research ethics arrangements through different organizational pathways. Some have dedicated research ethics councils or committees, some use specialized biomedical ethics bodies, and others regulate research ethics through broader institutional instruments.

The study is guided by the following principal research question: *How, and to what extent, are ERA-related principles relevant to research ethics formally institutionalized in the research ethics governance frameworks of Georgian universities?* Three subsidiary questions guide the analysis: *1. Which research ethics principles are incorporated into the selected institutional documents? 2. How are these principles translated into institutional authority, independence safeguards, ethical review procedures, monitoring, and accountability? 3. What common patterns and organizational variations characterize research ethics governance across the selected universities?*

The article contributes empirically by comparing formal research ethics governance across seven Georgian universities and methodologically by distinguishing normative recognition from regulatory and organizational embedding. It does not rank universities or assess their complete research-governance systems. Its claims are limited to what can be established from the selected research ethics documents.

2. Conceptual Framework: ERA Principles and Research Ethics Governance

The renewed ERA provides the broad normative context for the analysis. The Pact for Research and Innovation in Europe states that researchers, research processes, and research and innovation systems should comply with strict ethics and integrity rules and practices and identifies responsible and trustworthy research as a foundation of research excellence (Council of the European Union, 2021). The European Charter for Researchers likewise expects researchers to adhere to recognized ethical practices and the ethical standards applicable within national, sectoral, or institutional codes (Council of the European Union, 2023). These instruments establish a European policy expectation of responsible research while leaving substantial scope for national and institutional organization.

For the purposes of this study, only the research ethics component of this broader European policy environment is operationalized. The framework therefore focuses on whether universities have formal arrangements capable of protecting participants and other affected persons, evaluating ethical risks, safeguarding voluntary participation and confidentiality, managing reviewer conflicts of interest, and ensuring accountable ethical decision making. Broader research-integrity provisions are outside the unit of analysis unless they appear in a selected document and directly support the operation of research ethics review.

Institutionalization is conceptualized at three analytically distinct levels. Normative institutionalization occurs when principles such as dignity, autonomy, informed consent, confidentiality, fairness, non-maleficence, researcher responsibility, or impartiality are explicitly recognized. Regulatory institutionalization occurs when those principles are translated into concrete requirements, such as mandatory ethical review, informed-consent procedures, risk assessment, safeguards for vulnerable participants, or disclosure of conflicts of interest. Governance institutionalization occurs when principles and requirements are embedded in organizational structures through a formally constituted ethics body, defined jurisdiction, decision-making authority, independence safeguards, review procedures, monitoring, documentation, reporting, training, or quality assurance.

These levels are analytical rather than a rigid developmental sequence. A university may have detailed participant-protection procedures but limited provisions on public reporting, committee training, or review of committee performance. Organizational diversity is likewise not treated as a deficiency in itself. ERA

principles do not prescribe a single institutional template; the relevant issue is the credibility and depth of the arrangements through which ethical review is organized.

3. Methodology

3.1. Research Design and Data

The study employs comparative qualitative document analysis because its research question concerns formal institutionalization: what the selected university documents regulate, which responsibilities they assign, what ethics bodies they establish, and what procedures they prescribe. The unit of analysis is therefore the documented research ethics governance arrangement, not the university's research-governance system as a whole.

The data consists of seven institutional instruments: the research ethics regulation of the Faculty of Psychology and Educational Sciences at Ivane Javakhishvili Tbilisi State University (2022); the regulation of the Biomedical Research Ethics Committee at Tbilisi State Medical University (2007); the Research Ethics Code of Iakob Gogebashvili Telavi State University (2024); the Research Ethics Standard of East European University (n.d.); the Personnel Ethics Code of BAU International University, Batumi (2020), insofar as its provisions directly address ethical research conduct; the Research Ethics Regulation of Sulkhan-Saba Orbeliani University (2025); and the Scientific Research Ethics framework of Grigol Robakidze University (n.d.).

The cases were selected to capture variation in the formal organization of research ethics. Some documents establish specialized ethics bodies and prospective review systems, while others place research ethics within broader institutional codes. This variety is analytically useful because it shows different ways in which ethical review can become an institutional governance function. However, the documents are not assumed to constitute the complete set of policies governing research at each university. In particular, separate research-integrity, academic-integrity, misconduct, publication, or data-governance instruments may exist but are not assessed in this study.

3.2. Research Ethics Governance Assessment Framework

To systematize comparison, the study applies a Research Ethics Governance Assessment Framework derived from ERA-level ethical expectations and the governance features evidenced across the selected research ethics instruments (Council of the European Union, 2021, 2023). The framework does not represent an official ERA compliance instrument. It is an analytical device for examining the extent to which broad European expectations concerning ethical and responsible research are translated into formal university research ethics governance.

Five dimensions are examined. The first, *normative ethical alignment*, covers dignity and autonomy, voluntariness, informed consent, confidentiality and privacy, fairness, participant protection, proportionality of risks and benefits, researcher responsibility, and impartial ethical assessment. The second, *institutional responsibility and authority*, examines whether research ethics responsibility is assigned to an identifiable body with a defined mandate, appropriate expertise, and substantive decision-making powers. The third, *governance positioning and independence*, considers organizational position, appointment and membership arrangements, multidisciplinary participation, conflict-of-interest safeguards, recusal, and protection of ethical decisions from inappropriate influence. The fourth dimension, *ethical review and procedural capacity*, assesses application requirements, prospective review, risk-benefit analysis, consent procedures, safeguards for participants, decisions and revisions, amendments, continuing review, and monitoring. The fifth, *accountability, transparency, and oversight*, considers record keeping, minutes, reporting, committee training, quality assurance, complaints or appeals, and mechanisms for responding to non-compliance with ethics approval or review requirements.

3.3. Coding and Scope Conditions

The documents were analyzed through directed qualitative content analysis. Each indicator was assessed on a five-point ordinal scale: 0 indicated that no relevant provision was identified in the analyzed document; 1 indicated implicit or general recognition; 2 explicit formal recognition; 3 translation into a specific rule, responsibility, or procedure; and 4 structural and procedural embedding supported, where relevant, by defined authority, monitoring, oversight, or accountability. Scores were used as an analytical discipline rather than aggregated into an ERA compliance score or university ranking. Indicator-level

comparison makes it possible to distinguish, for example, between a general commitment to confidentiality and a system in which applicants must specify confidentiality safeguards, an ethics body evaluates them, and continuing oversight is possible.

A strict documentary rule was applied: where a mechanism was not identifiable in the document examined, it was coded as not evidenced in that document. It was not interpreted as proof that the university lacks the mechanism. This rule is especially important for research integrity, academic integrity, misconduct, publication ethics, and data governance, because such matters may be regulated through separate institutional instruments outside the present data. The study therefore makes no comparative claims about the completeness or quality of the universities’ wider research-integrity systems.

4. Results

4.1. *Normative Convergence in Research Ethics*

The clearest cross-case pattern is substantial convergence around core principles of research ethics. Across the selected documents, participant dignity and autonomy, informed consent, confidentiality, researcher responsibility, impartial assessment, and protection from harm recur as important normative expectations.

At TSU, the Faculty Research Ethics Council is responsible for evaluating research procedures according to ethical principles and protecting participants’ rights, dignity, and personal autonomy (Ivane Javakhishvili Tbilisi State University, 2022). TSMU similarly identifies participants’ safety, rights, dignity, autonomy, and welfare as central purposes of biomedical ethics review (Tbilisi State Medical University, 2007). Sulkhan-Saba Orbeliani University links research ethics procedures to internationally recognized ethical frameworks and requires relevant standards and guidelines to be considered in research involving humans or animals (Sulkhan-Saba Orbeliani University, 2025).

East European University provides a detailed participant-oriented framework addressing voluntariness, informed consent, confidentiality, autonomy, protection of vulnerable participants, justice, conflicts of interest, and proportionality between potential risk and anticipated benefit (East European University, n.d.). Grigol Robakidze University likewise includes participant protection, confidentiality, informed consent, independence, and scientific justification among its ethical principles (Grigol Robakidze University, n.d.). Where broader codes, such as the BAU Personnel Ethics Code, contain provisions relevant to ethical research conduct, those provisions are considered only to the extent that they bear directly on the research ethics questions analyzed here.

4.2. *Institutional Authority and Independence*

Several universities have institutionalized research ethics through specialized bodies with substantive review responsibilities. TSMU’s Biomedical Research Ethics Committee evaluates research plans, develops submission documentation, supervises ongoing studies, maintains records, provides educational support, makes institutional recommendations, and reports to the Academic Council; its regulation also states that the Committee is independent in decision making (Tbilisi State Medical University, 2007).

East European University defines its Research Ethics Committee as a multidisciplinary and independent collegiate body and provides for scientific, legal, ethical, and societal competence as well as independence from researchers and university administration (East European University, n.d.). TSU uses a faculty-level model incorporating academic representatives together with external or specialist representation, while Sulkhan-Saba establishes a university-level Research Ethics Council whose membership may include researchers, ethics or bioethics specialists, medical professionals, and relevant practitioners (Ivane Javakhishvili Tbilisi State University, 2022; Sulkhan-Saba Orbeliani University, 2025).

The comparison also shows that independence is more robustly institutionalized when a declaration of independence is accompanied by operational safeguards. TSU requires withdrawal from review in the presence of a conflict of interest, and Sulkhan-Saba requires disclosure and recusal before substantive review (Ivane Javakhishvili Tbilisi State University, 2022; Sulkhan-Saba Orbeliani University, 2025). Such provisions give procedural content to impartial ethical decision making.

4.3. Ethical Review and Continuing Oversight

The greatest differences concern the extent to which ethical principles are converted into a complete review process. TSMU requires submissions to address scientific justification, methodology, participant selection, risks, privacy safeguards, financial arrangements, conflicts of interest, future uses of data or biological material, and informed-consent documentation (Tbilisi State Medical University, 2007). Its oversight can continue after approval through reporting of amendments or issues affecting participant safety and rights, interim or final reports, and repeated review.

TSU similarly requires information on scientific rationale, methodology, the necessity of human participation, inclusion and exclusion criteria, risk, confidentiality, and informed consent. The Council may approve, conditionally approve, require revision, or reject a project and has post-approval monitoring authority (Ivane Javakhishvili Tbilisi State University, 2022). Sulkhan-Saba requires information on methodology, participant recruitment, foreseeable risks, rights and confidentiality, consent, incentives, and conflicts of interest, while East European University establishes detailed prospective assessment of participants' rights, safety and welfare, research quality, consent, privacy, and conflicts of interest (East European University, n.d.; Sulkhan-Saba Orbeliani University, 2025).

These differences demonstrate why normative similarity should not be equated with procedural equivalence. Institutionalization is deeper where ethical principles are connected to defined submission requirements, decision rules, amendment procedures, and continuing oversight.

4.4. Accountability and Governance of the Ethics Review System

A further distinction concerns whether institutional documents regulate not only applicants but also the functioning of the ethics review system. TSMU provides for internal quality review of committee activity: a temporary quality commission may examine a sample of reviewed research plans, assess adherence to procedures and timelines, formulate recommendations, and incorporate results into annual reporting (Tbilisi State Medical University, 2007).

East European University requires initial and continuing training of committee members and annual reporting to the rector, with reports or substantive summaries made publicly available subject to confidentiality safeguards (East European University, n.d.). Sulkhan-Saba requires formal minutes recording participation, agenda items, decisions, voting results, and supporting documentation and assigns responsibility for secure documentation to the Council secretary (Sulkhan-Saba Orbeliani University, 2025).

The broader pattern is that prospective ethical review is generally more developed in the selected documents than mechanisms for systematic evaluation, continuing training, public reporting, appeals, or quality assurance of the ethics body itself. This is a finding about the analyzed research ethics documents only; it does not establish that such mechanisms are absent elsewhere in the universities' governance systems.

5. Discussion

The findings suggest that ERA-related research ethics principles are being institutionalized in Georgian universities through diverse organizational forms. The strongest commonality lies at the normative level: dignity, autonomy, informed consent, confidentiality, participant protection, researcher responsibility, and impartial ethical assessment are widely reflected. Greater differentiation appears when these principles are translated into institutional authority, procedural depth, continuing oversight, and accountability.

This pattern supports the analytical distinction between formal recognition and governance embedding. A statement that research must respect ethical standards is meaningful, but it does not by itself demonstrate a developed ethics governance system. Institutionalization becomes deeper when ethical norms acquire an identifiable decision-making body, submission requirements, review criteria, conflict-of-interest safeguards, documented decisions, monitoring authority, and mechanisms for evaluating the quality of ethical review.

Research Ethics Committees and Councils therefore function as important organizational carriers of European-oriented ethics governance. They translate abstract principles into operational requirements: autonomy into informed consent; protection from harm into risk-benefit assessment; impartiality into conflict-of-interest and recusal rules; and accountability into documentation, reporting, monitoring, and quality review. The existence of a committee alone is consequently less informative than the governance architecture surrounding it.

Organizational diversity should not be interpreted as non-alignment. The cases include biomedical, faculty-level, university-wide, and broader institutional models. Since ERA establishes common values and

policy expectations rather than a mandatory university committee template, different organizational arrangements can embody comparable ethical principles. The more relevant question is whether they provide credible authority, expertise, independence, procedural safeguards, and accountability.

The narrower scope adopted here also changes how apparent documentary gaps should be interpreted. A research ethics regulation is not necessarily designed to govern plagiarism, authorship, publication practices, fabrication, falsification, data stewardship, or research misconduct. It would therefore be methodologically unsafe to infer weaknesses in a university’s research-integrity system merely because these matters are absent from an REC or IRB regulation. Assessing research integrity would require identification and analysis of the separate institutional instruments through which each university governs those matters.

For research ethics governance specifically, the findings indicate several areas in which formal institutionalization can be deepened without assuming a single organizational model. These include transparent appointment and recusal arrangements, multidisciplinary expertise, continuing education of ethics committee members, clear post-approval monitoring powers, systematic record keeping, annual or periodic reporting, complaints or appeals procedures, and periodic quality review of the ethics review process itself.

6. Conclusion

This study examined how ERA-related principles relevant to research ethics are formally institutionalized in the research ethics governance frameworks of seven Georgian universities. Using comparative qualitative document analysis, it distinguished normative recognition from regulatory and organizational embedding and assessed five dimensions of ethics governance: normative ethical alignment; institutional responsibility and authority; governance positioning and independence; ethical review and procedural capacity; and accountability, transparency, and oversight.

The analysis identifies substantial normative convergence. Core research ethics principles, including participant dignity and autonomy, informed consent, confidentiality, participant protection, researcher responsibility, and impartial assessment, are reflected across the selected documents. Their organizational translation is more differentiated. Several institutions have established specialized ethics bodies with defined mandates, structured review procedures, conflict-of-interest safeguards, documentation requirements, and continuing oversight, while provisions concerning committee training, public reporting, appeals, and systematic quality assurance are less consistently evidenced in the analyzed instruments.

Research ethics governance in the selected universities can therefore be characterized as uneven but substantive institutionalization of European-oriented ethical research principles. This conclusion does not amount to a finding of legal compliance with ERA, nor does it assess the universities’ complete research-integrity systems. ERA serves here as a normative policy reference, while the empirical claims are confined to the research ethics governance arrangements evidenced in the selected documents.

The study’s principal limitation is documentary scope. Research ethics regulations reveal how ethical review is formally designed but cannot establish how committees operate in practice. Moreover, universities may regulate research integrity, academic integrity, misconduct, publication, or data governance through separate instruments not included in this documentary corpus. Future research should therefore pursue two distinct extensions: empirical study of the implementation of research ethics governance through interviews, committee activity data, and anonymized decisions; and a separate analysis of research-integrity governance based on the relevant institutional documents.

References

- BAU International University, Batumi. (2020). Personnel ethics code [Institutional policy document].
- Council of the European Union. (2021). Council Recommendation (EU) 2021/2122 of 26 November 2021 on a Pact for Research and Innovation in Europe. Official Journal of the European Union, L 431, 1–9.
- Council of the European Union. (2023). Council Recommendation of 18 December 2023 on a European framework to attract and retain research, innovation and entrepreneurial talents in Europe, and replacing Recommendation 2005/251/EC (C/2023/1640). Official Journal of the European Union.
- East European University. (n.d.). Research ethics standard [Institutional policy document].
- Grigol Robakidze University. (n.d.). Scientific research ethics [Institutional policy document].
- Iakob Gogebashvili Telavi State University. (2024). Research ethics code [Institutional policy document].

Ivane Javakhishvili Tbilisi State University. (2022). Rules and procedures for the activities of the Research Ethics Council and determination of research ethicality, Faculty of Psychology and Educational Sciences [Institutional regulation].

Sulkhan-Saba Orbeliani University. (2025). Research ethics regulation [Institutional regulation].

Tbilisi State Medical University. (2007). Regulation of the Biomedical Research Ethics Committee [Institutional regulation].