

GUIDELINES ON COMPLIANCE FOR DUAL-USE RESEARCH ACTIVITIES WITHIN COLLABORATIONS OUTSIDE THE EUROPEAN UNION

SAPIENZA UNIVERSITY OF ROME



Guidelines prepared by the Panel on Dual-Use Research - Ethics Committee for Transdisciplinary Research (CERT) Sapienza University of Rome Courtesy translation V.1

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1. Context

1.1 The Values of Sapienza

Sapienza is guided by principles of respect for the freedom of research and the values recognized by the scientific community in the realms of ethics and research integrity.

This is highlighted in our Ethical Code, which states: "Sapienza recognizes, protects and promotes the values of the Constitution of the Italian Republic, especially regarding the development of culture and scientific and technical research (Article 9), the freedom of teaching (Article 33), the right of capable and deserving individuals to achieve the highest levels of education (Article 34), as well as in Title I of the University Statute." [Ethical and Conduct Code of Sapienza University of Rome DR 3430/2022].

Through the Research Integrity Commission, Sapienza adopted in 2020 an operational tool for matters related to research integrity, including ethical advice for the analysis and management of potential cases of research misconduct. To support ethical clearance activities, Sapienza established the Ethics Committee for Transdisciplinary Research (CERT) in 2021, which adheres to "a pluralistic perspective of ethical orientations, referencing national, EU, and international legal, deontological and ethical standards. In particular, CERT aims to safeguard: a) the rights, dignity, integrity and well-being of humans involved in research; b) respect for other living beings and environmental protection; c) freedom and the promotion of science and the ethics of science" [CERT Regulation DR 2014/2021].

The entire academic community is called to uphold these values and "to adopt **behaviours that promote the fundamental values of legality, solidarity and the rejection of all discrimination**; to ensure compliance with principles of fairness, impartiality and **protection of personal liberty and dignity, freedom of teaching, research and study**; to foster and encourage loyal collaboration, a spirit of service and sharing of ideals promote the principle of quality assurance as a fundamental factor for pursuing the institutional mission of the University"

[Ethical and Conduct Code of Sapienza University of Rome DR 3430/2022].

1.2. The International Context

Dual-use refers to the potential of products and technologies—developed for peaceful civilian purposes—to be misused. Specifically, dual-use products are goods, including software and technologies, that are designed and marketed for civilian use, but could also have military or improper applications. Export controls on dual-use goods have been introduced by the European Union as an essential tool for promoting peace and international security, as well as safeguarding human rights. These controls ensure that items with both civilian and military applications—such as advanced electronics, toxins, missile technologies or nuclear components—are not used in ways contrary to human rights. Authorization requests for exports outside the European Union reduce the



risk of such goods being employed in conflicts, human rights violations, or the proliferation of weapons of mass destruction. Exports in this area are regulated by commitments and obligations undertaken by EU member states within international non-proliferation agreements and multilateral export control regimes.

At the European level, the regulatory framework governing the export of dual-use goods is established by Regulation (EU) 2021/821, which significantly revised previous regulations. This revision considers developments in emerging technologies, ensuring more effective implementation and greater coordination among national authorities of member states and the European Commission. These controls can also be supplemented by national measures on dual-use products not included in European lists, adopted for public safety or concerns related to human rights.

Regulation (EU) 2021/821 introduced specific references to academia and research activities, emphasizing the obligations in this sector. It also drew attention to universities and research institutions conducting dual-use research, urging them to acquire the knowledge and methods necessary to verify the export of dual-use goods and services beyond EU borders—primarily through the **Internal Compliance Program (ICP)**, an internal compliance tool to manage legal risks arising from non-compliance with the regulation.

The Recommendation (EU) 2021/1700 of the European Commission on internal compliance programmes for controls of research involving dual-use items under, provided important guidance on implementing internal compliance programs. The Recommendation highlighted that "while research organizations require time to prepare and implement such measures, a systematic and proportionate approach to internal compliance measures for the control of exports of dual-use goods is essential to ensure compliance with the EU regulation on dual-use goods and complementary national provisions."

These Guidelines thus introduce the topic of dual-use technologies and a description of the Internal Compliance Program for dual-use research activities within collaborations outside the European Union. It is crucial to adopt proportional internal measures to minimize the risk of non-compliance, actively supporting regulatory adherence, assigning the necessary importance to compliance, and providing adequate resources to ensure commitments are met.

1.3. Purpose of the Guidelines

These Guidelines introduce the topic of dual-use technologies and a description of the Internal Compliance Program (ICP) for dual-use research activities within collaborations outside the European Union.

In 2021, Sapienza established the **Ethics Committee for Transdisciplinary Research (CERT)** to support ethical clearance activities. CERT was specifically created to offer advice, evaluations and reviews to scientific leaders, directly involved structures and governing bodies of Sapienza, ensuring that research aligns with ethical principles defined by international, national regulations, as well as Sapienza's Statute and Ethical Code. CERT's areas of focus include research in psychological, social, biological, environmental and technological fields (non-medical devices, artificial intelligence, dual-use technologies) and any research involving individuals or personal data



processing.

According to Article 2 of CERT's Regulation, "The Ethics Committee for Transdisciplinary Research, in carrying out its activities, adheres to national, EU and international legal, deontological, and ethical frameworks from a perspective of pluralism of ethical orientations. Specifically, it operates to safeguard:

- a) the rights, dignity, integrity and well-being of humans involved in research;
- b) respect for other living organisms and environmental protection;
- c) freedom and the promotion of science and the ethics of science."

The CERT regulation was later amended to include specific tasks related to dual-use research, as approved by the Academic Senate and the Administrative Council in resolutions no. 128/2024 (14 May 2024) and no. 158/2024 (28 May 2024). In particular, the CERT was formally integrated with at least one dual-use expert and, starting from June 2024, receives support from the newly established **Panel on Dual-Use Research**.

The **Panel on Dual-Use Research** (DR 1370/2024) operates according to shared guidelines and best practices at both European and national levels. Its specific tasks include:

- a) Supporting CERT in dual-use-related activities;
- b) Assisting with the implementation and application of European regulations on dual-use;
- c) Proposing and supporting training initiatives on these topics, targeting doctoral candidates, researchers, academic staff, and relevant administrative personnel;
- d) Promoting the implementation of nationally (MUR, CRUI) and EU-approved guidelines and regulations to University Governance.

The Panel on Dual-Use Research includes at least two CERT members, an administrative staff member from the Research Support Area with expertise in dual-use research regulations and at least two highly qualified dual-use experts, either internal or external to Sapienza.

The Panel is chaired by a Coordinator appointed by the Rector.

https://www.uniroma1.it/it/pagina/panel-su-tematiche-duplice-uso

1.4. Internal Strategy

The Panel on Dual-Use Research, established on June 18, 2024, outlined a work plan based on three pillars: **Informing**, **Training**, **Empowering**. The work plan includes the following actions:

a) Informing: raising awareness about dual-use research

• Communication campaign on the dual-use topic, aimed at the academic community;

b) Training: updating and providing operational tools for research management

- Enhancing training in research ethics targeted at PhD candidates as part of Soft Skills training
- Training program directed at administrative staff involved in research management within the Central Administration and Departmental areas, with reference to European dual-use regulations;



c) Empowering: establishing a chain of technical-scientific responsibility related to dualuse regulations

• Instruction on the implementation of European regulations on dual-use;

In July 2024, the Panel held six auditions with all the Faculties and the School of Aerospace Engineering. The goal of these auditions was to share the working methodology with the various Faculty members and gather their input.



2. Introduction to Dual-Use Technologies

Definition of dual-use:

Dual-use refers to the potential of products and technologies, developed for peaceful civilian purposes, to also have applications in the military sector or be used improperly.

Definition of dual-use products:

Dual-use products are goods, including software and technologies, that have civilian uses and are designed and marketed for this purpose, but could also have military applications. These products differ from armament materials as they are not specifically designed for military purposes; however, they could be employed in the design, development, production or use of chemical, biological, radiological, and nuclear weapons or their delivery systems.

List of dual-use products:

"Regulation (EU) 2021/821 introduces a comprehensive improvement to strengthen the previous system for controlling exports of dual-use technologies, addressing evolving security risks and emerging technologies. It expands cooperation among Member States and the Commission, imposes specific obligations on exporters, and introduces controls aimed at preventing human rights violations by surveillance technologies." [EU 2021/821]. The list of dual-use products is included in Annex I of European Regulation (EU) 2021/821, implementing international agreements on dual-use product control, particularly non-proliferation regimes in the chemical-biological sector (Australia Group), missile technology sector (Missile Technology Control Regime), nuclear sector (Nuclear Suppliers Group), Wassenaar Arrangement, the Chemical Weapons Convention (CWC), and the Biological Weapons Convention (BWC).

Below is a summarizing, non-exhaustive table of dual-use technologies listed in EU Regulation 821/2021. The complete and detailed list is available in the annexes referenced [EU 2021/821]. Additionally, it is recommended to refer to national lists; the current one was published by the Deputy Minister of Foreign Affairs and International Cooperation under Decree no. 1325/BIS/371 of July 1, 2024, establishing the National Control List for non-listed dual-use goods, pursuant to Article 9 of Legislative Decree December 15, 2017, no. 221 [Dec. 1325/2024].

Research areas	Dual-use descriptors
Biology and (nano)biotechnology	Human, plant and animal pathogens
	Toxins
	Biological protection, containment and handling equipment
Chemistry	Chemicals, polymers, lubricants and fuel additives
Advanced material science	Chemical manufacturing facilities, equipment and components such as pumps, heat
	exchangers, valves and distillation columns



	Chemical protection, containment and handling equipment
Nuclear physics and engineering	Nuclear reactors and specially designed or prepared equipment and components
	Nuclear material
Energy and environmental	Optical and acoustic sensors
technology	Cameras
Computer science and engineering	Source code for some listed acoustic data processing
Information and communications	Digital ruggedized computers
technology	Intrusion software related items
	Telecommunications systems, equipment, components and accessories (including interception and jamming)
	Information security hardware, software and technology (including encryption and cryptanalysis)
Avionics and aerospace engineering	Accelerometers
and design	Gyroscopes
	Navigation (receiving) systems
	Drones
	Launch platforms
	Satellites
	Aero gas turbine engines
	Ramjet, scramjet or combined cycle engines
Semiconductor	Integrated circuits
	Semiconductor manufacturing, testing or inspection equipment
	Wafer substrates
	(Computer-aided-design) software for semiconductors
Optical engineering	Lasers
	Optical sensors
	Imaging cameras
Robotics and process automation	Machine tools
	Robots, end-effectors and remotely controlled articulated manipulators
	Dimensional inspection systems



Additive manufacturing (3D printing)	Feedstock materials
	Manufacturing equipment
Quantum technologies	Quantum cryptography
Artificial intelligence and machine	Neural network integrated circuits
learning	Neural computers
	Electronic components
Naval technologies	Surface vessels
	Underwater vessels
	Underwater vision systems
	Power transmission and generation systems
Cyber-surveillance items	Mobile telecommunications interception equipment
	Internet surveillance systems
	Tools for the generation, command and control, or delivery of intrusion software
	Law enforcement monitoring software
	Digital forensic/investigative tools

3. Definition of terms

- Due diligence. Refers to a process of investigation or evaluation carried out by an individual or organization to gather information and analyse risks associated with a particular transaction or opportunity. Commonly used in financial and legal contexts, due diligence can also apply to other areas such as business partnerships, investments, acquisitions, collaborations, and research projects. It is a critical tool for risk management and informed decision-making across various settings, enabling stakeholders to operate with greater awareness and accountability.

- *Exporter.* Any natural or legal person, including researchers or partnerships, who physically ships, digitally transmits, personally transports, or makes dual-use products—including software and technologies—available outside the EU [Regulation EU 2021/821].

- *Exemptions from Dual-Use Controls.* The EU regulation on dual-use products includes exemptions specifying conditions under which listed products are not subject to control. For dual-use technologies on the lists, there are three possible exemptions: "technology" resulting from "basic scientific research," "technology" that is already "in the public domain," and the minimum quantity of information necessary for patent applications.

- Project. Defined as a complex set of activities that:
 - Relate to scientific research and/or education and/or the third mission;
 - Are funded following a competitive evaluation process through public or private grants;
 - Are bound by agreements, contracts, or conventions with the funding entity and/or other partners, with constraints on time, resources, and achievement of predefined results.;

- Research Projects in Competitive Calls. Projects partially or entirely funded by EU Framework Programs, such as those for Research and Innovation, Education and Training, Environment, or International Cooperation. International projects funded by international public or private entities (e.g., intergovernmental organizations, international agencies, foundations, academies, other entities, including those involving the university). Nationally funded projects through ministries, regional and local entities, research institutions and foundations—public or private.

- Commissioned Research. Research services or consultancy aimed at technical and/or scientific opinions, feasibility studies, technical and scientific assistance, development and/or creation of prototype systems and their qualification, research and development studies conducted on behalf of a private or public client and undertaken through participation in procedures governed by national or international



procurement regulations.

- Scientific Coordinator. Also known as Academic Coordinator, Principal Investigator, or Supervisor, this term refers to the individual responsible for the scientific activities proposed and implemented by Sapienza, as outlined in agreements with the funding entity.

- *Dual-Use Products.* Defined as products—including software and technologies that have both civilian and military uses under Regulation EU-2021/821 of the European Parliament and Council dated May 20, 2021. "Products—including software and technologies—that can be used both for civilian and military purposes and include products that can be employed in the design, development, production, or use of nuclear, chemical, or biological weapons, or their delivery systems. This includes all products that can have a non-explosive use as well as any use in the manufacturing of nuclear weapons or other explosive nuclear devices." [EU 2021/1700]

- Internal Compliance Program (ICP). Effective, adequate, and proportionate policies and procedures implemented by exporters to facilitate compliance with national and European regulations.

- *Basic Research.* Experimental or theoretical work undertaken primarily to acquire new knowledge of the fundamental principles of observable phenomena or facts, not primarily oriented towards specific practical objectives.

- Technology Readiness Level (TRL). Refers to the system for measuring the maturity level of a given technology without limitations to a specific discipline. Each technology project is assessed based on parameters for each technological level and then assigned a TRL evaluation based on progress. There are nine levels of technological readiness, with TRL 1 being the lowest and TRL 9 being the highest (Figure 1).





Figure 1: Technology Readiness Levels (TRL), tratto da [TRLNASA].



- *Technology.* Refers to the specific information required for the "development," "production," or "use" of dual-use products included in the lists. This means that, to be classified as listed dual-use technology, technical data or technical assistance must include specific information necessary for the development, production, or use of goods specified in categories 0 to 9 of Annex I of Regulation 821/2021.



Figure 2: TRL Levels and Export Controls a

4. Recommendations: General Principles

Managing research projects on Dual-Use Research involving non-European partners requires European universities to navigate a complex landscape of compliance rules and regulations, ensuring responsible research conduct while adhering to legal, ethical, and security standards.

While export controls for research under the dual-use category must be evaluated case by case and European and Italian export control regulations are frequently updated, the fundamental element in the compliance process is **researchers' awareness of the potential risks associated with their research**. Such awareness encompasses several aspects, including adherence to export control regulations, careful evaluation of the research's potential purposes and project partnerships through a due diligence process, and secure management of research data (data management plan).



Sapienza supports its academic community through actions in information, training, and empowerment, enabling them to maintain high academic standards consistent with current regulations.

Due Diligence for International Research

Due diligence in identifying research partners is a critical process that helps identify and mitigate risks related to security, reputation and regulatory compliance, especially in projects involving dual-use technologies.

In international collaborations, particular attention is recommended in establishing clear contractual agreements (such as memoranda of understanding) outlining compliance obligations concerning export controls and dual-use considerations. Clauses ensuring compliance with European and national regulations should also be included, anticipating possible changes to the lists of products and technologies. In case of doubts or sudden changes in initial conditions, researchers are encouraged to consult the appropriate offices to verify the compliance of activities and contractual clauses.

Compliance with Export Control Regulations

In terms of obligations under European Regulations [EU 2021/821], national decrees and Recommendations [EU 2021/1700], it is essential to verify the need for an export license when research (products, prototypes, technologies, technical assistance) is transferred abroad or made available outside the EU. Sapienza's Internal Compliance Programme (ICP) addresses this in detail in Articles 5 and 6 of these guidelines.

For its Internal Compliance Programme, Sapienza relies on CERT, within which a Panel on Dual-Use has been established. Requests for opinions from CERT can be submitted via the platform mentioned in section 7, either by the research's Scientific Coordinator or the Department. The Department may require a preliminary opinion from CERT before initiating project activities or approving the contract.

In general, it is necessary to ensure that technologies with potential dual-use applications intended for non-European partners are handled with due awareness, ensuring all required authorization procedures are followed. For a more detailed description, please refer to the documents listed at the end of this document:

[Int. UK 2020] [UE R&I interference 2022] [OECD Integrity 2022] [BAFA EC 2023] [Allea 2023] [UE 2024/3510] [UE Council 2024]



5. Recommendations for Research Projects in Competitive Calls

1. This article provides recommendations regarding research activities conducted within national, EU and international institutional funding programs that involve potentially dual-use research.

2. To ensure a conscious management of security risks in research, scientific coordinators may always request, even before submitting a project proposal, an ethical clearance from the Transdisciplinary Research Ethics Committee of Sapienza (CERT) regarding activities involving "dual-use products" or for which public safety reasons—including the prevention of terrorist acts or respect for human rights—might be considered.

3. If the project is funded by a financing entity legally based in non-EU countries and if the Technology Readiness Level (TRL) associated with the contract exceeds 2, it is strongly recommended that the scientific coordinator request an ethical clearence from CERT as soon as they are informed of the project's approval and, in any case, no later than one month after the contract is signed with the financing entities.

4. In cases where an ethical clearence is requested pursuant to the preceding paragraphs 2 and 3, in accordance with the methods indicated in Article 7 of these guidelines, CERT, with the support of the Panel on "Dual-Use Research," shall provide its resolution within 45 days of such request regarding the compatibility of project proposals or related contracts with current dual-use product regulations. The Committee will furnish the scientific coordinator with all necessary knowledge to make informed decisions regarding the security risks of the research and advise on the potential necessity of obtaining an export license from the competent authorities.



6. Recommendations for Commissioned Research

1. This article provides recommendations regarding potentially dual-use research activities carried out on a remunerative basis within agreements, contracts and conventions with third parties.

2. To ensure conscious management of security risks in research, the scientific coordinator of the contract or convention may always request an ethical clearence from the Transdisciplinary Research Ethics Committee of Sapienza (CERT) regarding activities and contractual services related to paragraph 1, or those involving public safety considerations, including the prevention of terrorism or respect for human rights.

3. If the counterparts of the contracts described in paragraph 1 are legally based in non-EU countries and if the Technology Readiness Level (TRL) associated with the contract exceeds 2, it is strongly recommended that the scientific coordinator of the contract or convention request an ethical clearence from CERT before submitting the approval request to the decision-making bodies of the spending centres.

4. In cases where an opinion is requested pursuant to paragraphs 2 and 3, in accordance with the methods indicated in Article 7 of these guidelines, CERT, with support from the Panel on Dual-Use Research, shall provide its resolution within 45 days of the request regarding the compatibility of the contracts described in paragraph 1 with current regulations on dual-use products. CERT will supply the scientific coordinator with all necessary knowledge to make informed decisions regarding security risks in research and indicate whether an export license needs to be requested from the competent authorities.

5. In respect of scientific autonomy and the freedom of international cooperation in research and innovation, the scientific coordinator may proceed with the request for contract approval by the decision-making bodies of the spending centres, providing detailed justification regarding any risks and critical issues identified by CERT in its opinion, which must be attached to the approval request.



Figure 3: Flowchart for Validation Requests to CERT for Commissioned Research



Figure 4: Flowchart of Contract Approval in the Department Council and Export License Request





7. Submission of Applications via the CERT Platform

The Ethics Committee for Transdisciplinary Research is responsible for ensuring that research conducted by Sapienza complies with the ethical principles defined by international and national regulations, as well as Sapienza's Statute and Ethical Code. Specifically, for potentially dual-use research, CERT relies on the Panel on Dual-Use Research.

Who Can Submit Applications to CERT?

Applications can be submitted by PhD candidates, research fellows, researchers, professors at Sapienza, or Department Directors. These applications will be reviewed according to CERT's public calendar. Thesis evaluations and research conducted by external researchers outside Sapienza are not considered.

How to apply to CERT?

Applications can be submitted via the Sapienza Research Call platform: <u>https://bandiricerca.uniroma1.it/sigeba/#/login</u> accessible using institutional email credentials. Detailed instructions for submission are available at the following link.

https://www.uniroma1.it/sites/default/files/field file allegati/manuale istruzioni per li nvio di una richiesta di valutazione etica al comitato etico per la ricerca trans disciplinare di ateneo_cert_0.pdf

The CERT convenes once a month, according to a public calendar.

Requesting a Dual-Use Application to CERT

The applicant has the freedom to request only the evaluation related to dual-use or the entire ethical evaluation by CERT. The applicant can choose from the following options: a) CERT Ethical Evaluation, filling in all applicable fields related to their research; b) Dual-Use Panel Evaluation (Feed 6); c) Both evaluations.



8. Reference Documents

[CodiceEtico2022] "Codice Etico e di Comportamento Sapienza" https://www.uniroma1.it/it/documento/codice-etico-e-di-comportamento

[CERT2021] "Comitato Etico per la Ricerca Transdisciplinare" https://www.uniroma1.it/it/pagina/comitato-etico-la-ricerca-transdisciplinare

[TRL-NASA] "Technology Readiness Levels" https://www.nasa.gov/directorates/somd/space-communications-navigationprogram/technology-readiness-levels/

[UE2021/821] "REGULATION (EU) 2021/821 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast)"

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0821

[UE2021/1700] "COMMISSION RECOMMENDATION (EU) 2021/1700 of 15 September 2021 on internal compliance programmes for controls of research involving dual-use items under Regulation (EU) 2021/821 of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items" https://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32021H1700

[UE2024/3510] "Council Recommendation of 23 May 2024 on enhancing research security"

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:C_202403510

[UE Council 2024] Proposal for a Council Recommendation on enhancing research security

https://research-and-innovation.ec.europa.eu/news/all-research-and-innovationnews/eu-member-states-adopt-recommendations-enhance-research-security-2024-05-23_en

[Dec. 1325/2024] Decreto del Vice Ministro degli affari esteri e della cooperazione internazionale n. 1325/BIS/371 del 1° luglio 2024, volto all'istituzione dell'Elenco nazionale di controllo per i beni a duplice uso non listati, ai sensi dell'art. 9 del decreto legislativo 15 dicembre 2017, n. 221

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https://www.oecd.org/en/publications/integrity-and-security-in-the-global-researchecosystem_1c416f43-en.html

[BAFA EC 2023] Export Control and Academia - Manual - Federal Office for Economic Affairs and Export Control (BAFA) Novembre 2023 <u>https://www.bafa.de/SharedDocs/Downloads/EN/Foreign_Trade/ec_manual_export_</u> <u>control_and_academia.html</u>

[Int. UK 2020] Managing risks in internationalization, Universities UK 2020 https://www.universitiesuk.ac.uk/what-we-do/policy-andresearch/publications/managing-risks-internationalisation

[UE R&I interference 2022] Tackling R&I foreign interference. Staff Working Document European Commission Directorate-General for Research and Innovation 2022

https://op.europa.eu/en/publication-detail/-/publication/3faf52e8-79a2-11ec-9136-01aa75ed71a1/language-en

[Allea 2023] The European Code of Conduct for Research Integrity The European Code of Conduct for Research Integrity - ALLEA