



RCSI

**ROYAL
COLLEGE
OF SURGEONS
IN IRELAND**

RCSI Internal Compliance Program/ Export Control Policy

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1. Purpose

Export controls are legal requirements designed to prevent the unauthorized use or proliferation of certain goods, technologies, and services (see appendix 1 for examples). The European Union (EU) enforces export controls on sensitive items to prevent the spread of weapons of mass destruction, safeguard regional stability, combat terrorism, and protect human rights and compliance is critical. Researchers must understand their responsibilities to ensure adherence to export control laws.

Violating export control laws is a serious offence, with penalties including fines or imprisonment. Both individuals and institutions can be prosecuted. In Ireland, the Department of Enterprise, Trade and Employment (DETE) is responsible for investigating breaches. Any violation could also cause significant reputational damage to RCSI.

Universities are subject to export controls in the same way as any other organisation, regardless of the reason or motivation for the export. If a university exports a listed item, or exports technical assistance or knowledge relating to a listed item (collectively referred to as 'controlled products'), it must obtain a licence in advance, regardless of the intended use. While Academic freedom is a fundamental right guaranteed by the Charter of Fundamental Rights of the European Union and the Universities Act 1997, academic freedom does not exempt researchers and Universities from complying with the export control regulations.

2. Scope

This Internal Compliance Program (ICP)/ Export Control Policy outlines the procedures and measures implemented to ensure compliance with EU and national export control laws, particularly those related to dual-use goods and technologies. These regulations are outlined in the EU Commission Recommendation (EU) 2021/1700.

The Policy will be reviewed and updated annually by the Office of Research and Innovation (ORI).

3. Export Control screening Process

Researchers are primarily responsible for determining whether an export license is required for their activities, as they are most familiar with the technical specifications and application of their research. The following procedure helps researchers make this assessment:

Procedure

i. Training Requirement:

- a. All researchers must complete the [Export Controls Training module on Moodle](#) to understand what product or activities are subject to export control regulations.

ii. Assessment of Research:

- a. Researchers must assess their research activities as early as possible to determine whether they fall under export control regulations. A wide range of research activities may be affected by export controls, with examples provided in Appendix I.

iii. EU Dual-Use and Military Lists:

- a. Researchers should review the EU's lists of restricted products and activities (military and dual-use lists) to assess whether their research is affected. Research areas most likely to be impacted are listed in Appendix II.

- iv. **ORI Review and Assessment:**
 - a. The ORI will review the researcher's assessment and document the process. This ensures proper record-keeping and helps guide the researcher's decision.
- v. **Decision on License Requirement:**
 - a. After reviewing the information, the ORI, in collaboration with the researcher, will decide if an export license from DETE is needed. The process to obtain a licence could take several weeks, so researchers should assess and apply for a license as early as possible.
- vi. **Next Steps Based on the Decision:**
 - a. No License Required: If no license is required, the ORI will record the assessment, and no further action is needed.
 - b. Further Clarification Needed: If there are any uncertainties, the ORI will consult with relevant support units for additional guidance.
 - c. License Required: If a license is necessary, the ORI will assist the researcher in applying for the license via the online portal.
- vii. **License Issuance and Compliance:**
 - a. Once the DETE issues the license, the ORI will discuss the license terms with the researcher, including record-keeping and audit responsibilities.
- viii. **Export Compliance:**
 - a. Exports cannot proceed until the license is issued. The export must comply with all terms specified in the license.
- ix. **Freight Forwarding Compliance:**
 - a. If exporting physical items through a freight forwarding service, ensure that the service meets professional standards. Provide the forwarding agent with written instructions, including license details, routing requirements, and documentation responsibilities.

4. Training and Awareness

RCSI offers a training program on export controls, consisting of an introductory presentation and a [detailed training module](#) available on Moodle. The training program is designed for staff, students and researchers across the university.

- i. **Comprehensive Training:** Developed by PwC in 2022 for use across Irish higher education institutions, the video (38 minutes in total) covers essential export control concepts, including classification systems and worked examples. A certificate is awarded upon completion.
- ii. **Export Control Section of researcher handbook:** The Export Control section on the RCSI researcher handbook contains relevant legislation, guidelines, and updates on dual-use items.

5. Organizational Responsibilities

All RCSI employees, researchers and students of RCSI must ensure that they fully comply with this Export Control Policy/ICP. Failure to comply with any trade-related rules may result in fines, criminal prosecution, product recalls, suspension, or revocation of RCSI's import or export privileges and a serious disruption of its research activity.

Any questions in relation to export controls can be directed to exportcontrol@rcsi.ie

Different units within RCSI have distinct responsibilities dependent on their function and as detailed below:

Role	Responsibility
All departments	<ul style="list-style-type: none"> • Declaration of export control compliance as part of governance reporting.
Office of Research and Innovation	<ul style="list-style-type: none"> • Overall compliance, including training and ensuring awareness of RCSI personnel. This includes ensuring training on export controls is made available to all RCSI researchers. • Oversight of export control requirements. • Maintaining a list of export control applications and log of issues encountered or corrective actions suggested with regard to this policy/ICP. • Reporting of export control compliance as required by the institution. • Developing and reviewing this policy on an ongoing basis and to incorporate any operational or compliance related changes within the university. • Advising on export control and assisting with associated queries.
ORI contracts unit	<ul style="list-style-type: none"> • Informing and including standard contract clauses on export controls to be used in university contracts.
All researchers who are potential exporters (in particular principal investigators / research supervisors).	<ul style="list-style-type: none"> • Familiarise themselves with the RCSI export controls guidance documents and using diligence to determine whether their project requires any export control considerations. • Notifying the ORI (exportcontrol@rcsi.ie) as early as possible if there are likely to be any export control requirements associated with their project. • Preparing an export control licence application if one is required and providing information to the ORI to support the application process. • Engaging in on-going training and education to maintain their awareness of export control requirements and to help them follow applicable regulations and watch for violations or issues.
Head of Departments/Schools	<ul style="list-style-type: none"> • Raising awareness of this policy/ICP and ensuring compliance of their respective personnel, in particular principal investigators / research supervisors. Principal investigators and supervisors are responsible for knowing whether any product, including technology (e.g. know-how), being used in, or resulting from, their research, or the research of students they are supervising, is subject to export controls. • Monitoring local compliance of export control requirements at pre- and post-award

6. Performance review, audits and corrective actions

The Trade Licensing & Control Unit of DETE may inspect export licenses to ensure compliance with their terms. The ORI, RCSI Legal Counsel, and the researcher will participate in inspections as necessary.

The ORI will conduct annual internal audits of a sample of active licenses to assess compliance and improve procedures.

Any suspected violations of export control laws must be reported to the ORI via exportcontrols@rcsi.ie. Violations may lead to disciplinary actions under RCSI's Disciplinary Procedures or be reported to the DETE and an Garda Síochána.

7. Recordkeeping and Documentation

The ORI is responsible for maintaining accurate records of all export control assessments and licenses, stored securely on Sharepoint. Key records include:

- Training completion records (completion recorded on Moodle)
- Records of outreach and communications
- Export control assessments via the online tool
- Export license applications and outcomes
- Ancillary documents (e.g., contacts, item descriptions)

These records will be retained for a minimum of 6 years or as required by the license.

8. Physical and Information Security

RCSI is committed to preventing unauthorized access to or removal of dual-use items. The RCSI IT Security Policy ensures the protection of our IT resources and data, with technical measures such as malware protection, intrusion detection, and network stability services. These measures are updated as needed to address emerging cybersecurity threats.

Appendix I: A non-exhaustive list of scenarios where export controls may apply:

A wide range of research activities could trigger dual-use export control, as indicated in the illustrative list from the EU guidance document (see following page for more)¹:

- changing the host spectrum of lumpy skin disease virus to include human reservoirs;
- multispectral imaging camera sensors for data collection of crops;
- laser-based next-generation uranium enrichment technology as a potential alternative for the industrial enrichment that involves gaseous uranium in centrifuges;
- 3D printing of materials for energy applications;
- prototype drone with spraying system for combatting Eastern equine encephalitis virus;
- autonomous scientific underwater vessel that collects data automatically in deep sea regions; and
- Publication of the design concept for a UAV/drone.

¹<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2021:338:FULL&from=EN>

Research scenarios of where export controls may come into place

The following are scenarios where dual-use export controls may come into place. The list is non-exhaustive.

Scenario	What does the EU dual-use Regulation say?	To be considered as well
Teaching, consulting, collaborating or working on research involving dual-use items <u>inside customs territory of the Union</u> with visiting third country researchers	<ul style="list-style-type: none"> — The EU dual-use Regulation does not foresee controls for non-EU persons accessing dual-use items inside the customs territory of the Union. Hence, no licence is needed as long as the controlled dual-use items remain inside the customs territory of the Union. When the visiting third country researcher returns home with access to (or in possession of) the controlled dual-use item, then a licence is needed. 	<ul style="list-style-type: none"> — In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. — A licence may be required in case a sanctioned entity or a natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions.
Teaching, consulting, collaborating or working on research involving dual-use items <u>outside customs territory of the Union</u>	<ul style="list-style-type: none"> — The EU dual-use Regulation does not foresee controls for EU persons engaged outside the customs territory of the Union in research involving dual-use items. Hence, no licence is needed in principle <i>if there is no access to controlled dual-use items from within the customs territory of the Union</i>. 	<ul style="list-style-type: none"> — In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. — A licence may be required in case a sanctioned entity or natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions.
Organising inside customs territory of the Union a (virtual) conference/meeting/seminar/... or presenting at a (virtual) conference/meeting/seminar/... on research involving dual-use items	<ul style="list-style-type: none"> — The EU dual-use Regulation does not foresee controls for non-EU persons accessing dual-use items inside the customs territory of the Union. Hence, no licence is needed <i>if the controlled dual-use items remain inside the customs territory of the Union</i>. When the visiting third country researcher returns home with access to (or in possession of) the controlled dual-use item, then a licence is needed. — If the conference/meeting/seminar is virtual and transmitted to a destination outside of the EU, then a license is needed for that part of the research that involves controlled dual-use items. 	<ul style="list-style-type: none"> — In some national cases, a technical assistance licence is required — It is a good compliance practice to warn participants of licence requirements when exiting the customs territory of the Union with the controlled item(s). — A licence may be required in case a sanctioned entity or natural/legal person of a sanctioned destination seeks cooperation inside the customs territory of the Union. In some cases such cooperation is prohibited according to EU sanctions.
Organising outside customs territory of the Union a (virtual) conference/meeting/seminar/... or presenting at a (virtual) conference/meeting/seminar/... on research involving dual-use items	<ul style="list-style-type: none"> — The EU dual-use regulation does not foresee controls for EU persons engaged outside the customs territory of the Union in research involving dual-use items. Hence, no licence is needed in principle <ul style="list-style-type: none"> — <i>if orally presented, even when recorded on the spot, as long as there is no access to controlled dual-use items from within the customs territory of the Union.</i> 	<ul style="list-style-type: none"> — In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. — A licence may be required in case a sanctioned entity or a natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions

	<ul style="list-style-type: none"> — if accompanied by presentation or other conference material where the information is not meeting the controlled technology threshold(s). — The EU dual-use regulation requires a licence, — if there is access to controlled dual-use items from within the customs territory of the Union. — if accompanied by presentation or other conference material (carried in paper, on laptop or other physical carrier such as USB stick) that contains controlled dual-use technology. 	
Publishing listed dual-use technology	<ul style="list-style-type: none"> — A publication including technology that meets the thresholds for dual-use control needs an export authorisation. The intention to publish (and thus the act of publishing) is not enough to be considered to be in the public domain and is therefore not exempted from control. The export control authorities rely on the due diligence of research organisation to screen prepublications in sensitive research areas. — In case a (draft) publication (or raw data) meets the thresholds for containing export controlled dual-use technology it is subject to export controls. This applies to both the pre-publication phase and to the actual publication phase. In principle, this can also apply to Master or PhD thesis that meet the controlled technology threshold(s). 	The researcher or research organisation could consider to amend or omit the specific parts that contain the controlled technology or restrict the access to these specific parts. If mitigation is not feasible the researcher or research organisation should contact the competent authority how to fulfil the licence requirement (e.g. individual licence application).
Patented information and information for patent application	<ul style="list-style-type: none"> — No licence is needed in principle, as the export of patented information that is fully disclosed on the public record is considered to be “in the public domain” and hence exempted from export controls. — No licence is needed for the export of the minimum necessary information for patent applications. 	
Export of tangible dual-use items (goods), including prototype design and second-hand lab equipment	<ul style="list-style-type: none"> — Research organisations may (re)sell, donate or lend dual-use items or temporarily export them for their own research projects. Regardless whether the items are new, a prototype or second-hand, they require a licence for export if listed in Annex I and for intra-EU transfers if listed in Annex IV of the EU dual-use Regulation. 	

Appendix II: Research areas that are more likely to be impacted by dual-use export control²

The following research areas are more likely to be impacted by dual-use export control than other research disciplines. Please note that this list is non-exhaustive and may serve as (non-binding) tool to more easily identify relevant research. In this Appendix, the dual-use descriptors (right column) are rather general in nature. Specific export control comprising sharp technical parameters are summarized in the [Annex I to the EU dual-use Regulation](#), which should be consulted primarily.

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2021:338:FULL&from=EN>

Appendix 2

Research areas that are more likely to be impacted by dual-use export controls

The following research areas are more likely to be impacted by dual-use export controls than other research disciplines. Please note that this list is non-exhaustive and may serve as (non-binding) tool to more easily identify relevant research. In this Appendix, the dual-use descriptors (right column) are rather general in nature. Specific export controls comprising sharp technical parameters are summarized in the Annex I to the EU dual-use Regulation, which should be consulted primarily.

Research areas	Dual-use descriptors
Biology and (nano)biotechnology	Human, plant and animal pathogens Toxins Biological protection, containment and handling equipment
Chemistry Advanced material science	Chemicals, polymers, lubricants and fuel additives 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 technology	Optical and acoustic sensors Cameras
Computer science and engineering Information and communications technology	Source code for some listed acoustic data processing Digital ruggedized computers 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 and design	Accelerometers 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 learning	Neural network integrated circuits 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