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RESEARCH ARTICLE

Organizational structures and processes for research ethics and integrity: case study by the European University of the Seas (SEA-EU) Alliance

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Aim: To explore the structures and processes for research ethics and integrity among the universities that are a part of the European University of the Seas (SEA-EU) Alliance.

Methods: Data from the public websites or experts from the six universities of the European University of the Seas (SEA-EU) Alliance: University of Cádiz (Spain), University of Western Brittany in Brest (France), University of Kiel (Germany), University of Gdańsk (Poland), University of Split (Croatia) and University of Malta (Malta) were collected. We followed the approach of the EC Mutual Learning Exercise on Research Integrity and the country report cards at The Embassy of Good Science.

Results: We identified similarities and differences regarding research infrastructure, funding, strategy, research governance, compliance, integrity, regulations, and measures to promote good scientific practices and open science at the country level. The universities that are partners in the SEA-EU Alliance differed in the research capacity, expressed as the number of higher education institutions in the country, number of full-time researchers, gross expenditure on research and development, number of grants as well as in the structures and processes at the institutional and national levels for research ethics and research integrity. The differences in the research ethics and integrity frameworks at individual universities were related to the national legislation but also to the national and institutional incentives to promote responsible research.

Conclusions: In collaborative research, it is necessary that partner universities respect the differences between their organizational and national ethical and integrity frameworks, and establish the processes for ethics approval at the level of the Alliance in order to carry out joint research activities in accordance/conformity with ethical standards for scientific research and good scientific and publishing practice. The same is true for the investigation of research misconduct allegations at the Alliance level.

Keywords: research ethics; research integrity; SEA-EU Alliance; good science; research infrastructure; research funding-expenditures

Introduction

Due to the growing number of research misconduct scandals, pervasive incentive to publish, and numerous situations in which conflicts of interest play a role in science, research integrity is of increasing importance for research organizations (ALLEA, 2017). It is not an isolated, national problem – integrity in scientific research is an international concern of the global scientific community (Aschwanden, 2007). Research integrity has been a part of the scientific discourse for many years and evolved to a separate research field over the past 20 years (Bonn & Pinxten, 2019), and especially in Europe (Bendiscioli & Garfinkel, 2020). While the universities included in this study have not experienced major misconduct scandals, it is important to increase the awareness of research integrity, forms of research misconduct that can be avoided are fabrication, falsification, and plagiarism, inappropriate authorship practices, lack of proper data management, or withholding of research findings (Roje, Elizondo, Kaltenbrunner, Buljan, & Marušić, 2022).

Research ethics and research integrity are two very connected but separate concepts. According to the latest definition from the European Network for Research Ethics and Integrity project (Penders et al., 2018), research ethics addresses the application of ethical principles or values to various issues and fields of research. This includes the ethical aspects of the design and conduct of research, the way human participants or animals within research projects are treated, whether research results could be misused for criminal purposes, as well as to the aspects of scientific misconduct. Research integrity is recognized as the attitude and habit of the researchers to conduct research according to appropriate ethical, legal and professional frameworks, obligations and standards.

Research ethics and research integrity are a part of the critical organizational framework to ensure that research at research organizations, including academic institutions, is ethical and responsible. In the setting of international collaborations and inter- and multi-disciplinary research, academic organizations are challenged not only by the need to develop policies and guidelines for research ethics and research integrity but also to harmonize existing procedures when it comes to collaborative efforts, such as transnational Alliances based on creating the future of higher education (Ursić et al., 2022). Since the Alliances of European universities are oriented toward the goals of joint research, with the ambitious vision of an innovative, globally competitive and attractive European Education Area and European Research Area (European Commission, n.d.-c), it is necessary to set the principles of research ethics and research integrity to ensure responsible research in the context of different local legal and organizational regulations. This is especially important given the fact that European universities are oriented to the creation of a single legal entity in the future so that they can mutualize their strengths, make common strategic decisions, act together with a legal personality, and facilitate pooling the resources, activities and data (SEA-EU – The European University of the Seas, n.d.).

The Alliances of European Universities are an initiative of the European Commission, which came to life in 2019 (European Commission, n.d.-c). This initiative has an ambitious mandate aimed to trigger unprecedented levels of institutional cooperation between higher education institutions, making such collaborations systemic, structural, and sustainable. It aims to encourage the emergence of bottom-up Alliances of universities across

Europe, which will enable students to combine studies in several countries (European Commission, n.d.-c). In line with the priorities of the European Education Area by 2025, these European Universities intend to (European Commission, n.d.-c):

- promote common European values and a strengthened European identity by bringing together a new generation of Europeans able to cooperate within different cultures, languages, and across borders, sectors, and academic disciplines;
- reach a substantial leap in quality, performance, attractiveness, and competitiveness of European higher education institutions, and contribute to the European knowledge economy, employment, creativity, culture, and welfare by making the best use of innovative pedagogies and striving to make the knowledge square a reality.

European Universities are foreseen to be a key driver that will boost the quality of higher education and where possible strengthen its link to the research and innovation landscape in Europe and its outreach towards the society and economy (European Commission, n.d.-c).

The European University of the Seas Alliance was formed between six universities in 2019: University of Cádiz (Spain), University of Western Brittany in Brest (France), University of Kiel (Germany), University of Gdańsk (Poland), University of Split (Croatia) and University of Malta (Malta). One of the key activities planned by the SEA-EU Alliance is to transform the involved universities through "sharing educational programs, analysis, policies, procedures, services, databases, infrastructure, research networks, and governance" (SEA-EU – The European University of the Seas, n.d.). The community of more than 10,400 researchers is a particular challenge for establishing ethical principles. One of the goals of the Alliance is to foster open educational resources, open science, and open data to communities and the world at large to expand the SEA-EU university model beyond borders. The Quality and Ethics Subcommittee has been set up as one of the main organs of the Alliance, with the aim to supervise that the ethical execution takes place by this project, and to signalize important deviations in terms of results, quality, timing, and resources spent. The Quality and Ethics Subcommittee also works on implementing and managing the ethical and legal issues of all procedures in the project, ensuring that the guiding principles and the main procedures regarding privacy, data protection, security, legal issues, and ethical challenges are being followed (SEA-EU – The European University of the Seas, n.d.).

This paper presents a qualitative analysis of secondary data sources to assess the existing structures and procedures for research ethics and research integrity at the universities that make up the European University of the Seas (SEA-EU) Alliance, in order to provide the baseline data for further development of the Alliance.

Methods

The data were collected following the approach of the EC Mutual Learning Exercise on research integrity (European Commission, n.d.-d) from 2018–2018, presented also at The Embassy of Good Science (n.d.), an using the public and internal national online sources. The Embassy of Good Science is a platform where the community can share experiences

and insights, deepen understanding, and continuously contribute to the development of good science (The Embassy of Good Science, n.d.). Ethical framework reports by country can be found on the platform (all data presented in **Table 1**). The data on Croatia, France, and Spain were available on the platform, while the data for the remaining three countries (Germany, Poland, and Malta) were collected according to the proposed methodology by searching available Internet sources (The Embassy of Good Science, n.d.).

The data search was conducted in the period from January to November 2022.

Table 1. The presentation of all country reports data on research ethics (RE) and Research integrity (RI) available on The Embassy of Good Science platform*

Research infrastructure	Research funding	Research strategy	Research governance, compliance, and integrity	Laws and regulations	Measures to promote good scientific practices and open science
Number of full-time researchers	Gross expenditure on research and development and its distribution across sectors (private, high-education, state, etc.)	National Research Strategies	National bodies for RI and RE and their scope	Laws and regulations regarding Research ethics and research integrity and their scope	RI and RE training
Number of higher education institutions (public, private)	Number of grants from EC programs and total funding in Euros		Organization of RI and RE at universities		RI and RE dialogue and communication
Several non-university research organizations, technology centres, private companies, etc.			Existence of research ethics committees (national, institutional, differences for different research fields, etc.		RE/RI incentives

*Source: The Embassy of Good Science (n.d.).

Results

We present the information about the general research framework and structures and processes for research ethics and research integrity for the individual members of the SEA-EU Alliance.

University of Split, Croatia

Infrastructure for research

There are nine public and three private universities in Croatia. The list of all universities with associated links, together with the names of the cities where they operate is available in The Embassy of Good Science (n.d.).

As stated by Kršul (2017) on the Embassy of Good Science, based on the information provided by the Ministry of Research and Education, there are 23,449 registered researchers, where 11,481 of them correspond to the definition of researchers in Croatia. Further on,

according to the Information System of Science of the Republic of Croatia (CroRIS, n.d.), there are 192 registered Scientific Institutions in Croatia.

Expenditure and number of grants from European Commission programs in Croatia

When analysing research infrastructure (gross expenditure on research and development and its distribution across sectors (private, high-education, state, etc.), number of grants from EC programs and total funding in Euros, the gross expenditure was €76.231,740, with 21 signed grants receiving €121.9 million in the EU's H2020 program, as well as 8 H2020 ERC grants receiving €8.87 million.

Research strategies, bodies for research ethics and research integrity

The Parliament of the Republic of Croatia has adopted The Strategy for Education, Science, and Technology 2014–2020 and the Strategic Plan for the period 2020–2022 (**Table 2**). In the past, the National Committee for Ethics in Research and Higher Education and The Committee for Ethics in Research and Higher Education was established at the national level. The new Act on Scientific Activity and Higher Education (Zakon o visokom obrazovanju i znanstvenoj djelatnosti, 2022), does not provide for such a national body, but leaves the responsibility for ethics to the organizations, with the National Council for Science providing recommendations for ethics.

The University of Split has the Committee for Ethics at the university level and Ethics Committee at the level of faculties and departments. The international dimension of ethical concerns has been launched within the SEA-EU Alliance project, where the QES is tasked with monitoring and managing ethics and quality issues.

Table 2. Bodies for research ethics and research integrity (RE/RI) and scope of their action in Croatia*†

Body for RE/RI	Scope
Ministry of Science and Education in Croatia (Ministry of Science and Education, 2014)	The Strategy for Education, Science, and Technology 2014–2020
The Committee for Ethics in Research and Higher Education	There are no recent publicly available decisions of the Committee. Institutions have ethics committees that deal with research misconduct allegations. They are not public, except when there is a media release. There are no recent publicly available decisions of the Committee. Institutions have ethics committees that deal with research misconduct allegations. They are not public, except when there is a media release.
The Ethics Committee at the University of Split (Sveučilište u Splitu, 2022)	The Ethics Codex was delivered in 2009 and updated in 2020 (Sveučilište u Splitu, 2009)
The Ethics Committee at the faculty and departments level	It is up to each faculty/department to establish a relevant ethics working body.
The quality and ethics subcommittee at the SEA-EU Alliance	The body is focused on quality assurance and ethics compliance activities

*Abbreviations: MZO – Ministry of Science and Education, UNIST – University of Split.
†Source: The Embassy of Good Science (n.d.).

Laws and regulations

The main legal document regarding research ethics and research integrity and their scopes are The Law on Science and Higher Education and the Ministerial Ordinance on Good Clinical Practice for Drugs (with regard to clinical trials) (**Table 3**).

Table 3. Laws and regulations regarding research ethics and research, development and innovation in Croatia*

Law/regulation	Scope
The Act on Scientific Activity and Higher Education (Zakon o znanstvenoj djelatnosti i visokom obrazovanju, 2022)†	Stipulates the system of research activity and higher education and indicates one of the pillars of research activity, which is the ethics of researchers.
Ministerial Ordinance on Good Clinical Practice for Drugs (Ministarstvo zdravstva, 2021)	Provides standards serve as Good Clinical Practice for Drugs, including the registration of clinical trials.

*Source: The Embassy of Good Science (n.d.).
†Since October 15th, 2022, this law has been replaced by the new Act on Scientific Activity and Higher Education (Zakon o znanstvenoj djelatnosti i visokom obrazovanju, 2022).

Training and promotion of ethics and research integrity

There is no available systematic training on research integrity, except at some research organizations, mostly at the postgraduate (doctoral) level. All university constituents have access to online tools for checking the authenticity of written texts (articles, theses, etc). There is low interest and public communication regarding research ethics/research integrity dialogue. Research ethics/research integrity assessment is a part of the formal and mandatory accreditation and re-accreditation processes carried out by the Agency for Research and Higher Education, but there is no systematic oversight.

Process for ethics approval at the University of Split

The Ethics Committee of the University of Split is appointed by the Senate of the University of Split. The faculties/departments of the University of Split establish their own Ethics committees in accordance with the law, the Statute of the University, the statute of the institution, and the Ethics Code.

At the University level, there is an Ethics Code approved by the Senate from July 2009 and the Ethics Committee of the University of Split (Sveučilište u Splitu, 2009). In 2020, amendments to the Ethics Code were adopted as the strategic document (Sveučilište u Splitu, 2022).

At the University of Split, the ethics approval procedure occurs at the faculty/department level. Similar principles have been implemented in most of the faculties/departments:

- The researcher submits the description of the research study and relevant documentation requested by the Ethics Committee of the faculty or department.
- Some faculties/departments require the approval of the Ethics Committee only when research involves human participants.

- The Ethics Committee at the faculty/department level has to give an opinion within 30 days from the day of submitting the request (in most cases).

In the case of the School of Medicine, the University Department of Health Studies, and some other components of the University, the documentation for the ethics approval is more complex, especially in clinical research involving human participants. The documentation includes the study protocol, templates for informed consent forms and information material, the provisions of the General Data Protection Regulation, as well benefits and risks assessment (Sveučilište u Splitu, Sveučilišni odjel zdravstvenih studija, n.d.; Sveučilište u Splitu, Medicinski fakultet, n.d.).

For clinical trials involving medical drugs and medicinal products, the ethics application has to be obtained from the National Central Ethics Committee, which is hosted by the Croatian Agency for Medicinal Products and Medical Devices of Croatia (Croatian Agency for Medicinal Products and Medical Devices of Croatia, 2022). This applies both to commercial and academic trials of medicinal products. Clinical trials involving interventions other than medicines and medicinal products are dealt with the local (organizational) Ethics Committees.

A similar procedure exists also at the university level when the request is addressed to the University Ethics Committee (in situations when the projects and activities are performed at the university level).

At some faculties/departments, the process for ethics approval is the same for diploma theses as it is for any other research study, and the student and/or the student's supervisor submit the request (Sveučilište u Splitu, Medicinski fakultet, n.d.).

For example, at the University department for Health Studies, the ethics procedure is as follows (Sveučilište u Splitu, Sveučilišni odjel zdravstvenih studija, n.d.):

1. Any research conducted as part of a final or diploma thesis must, as part of the standard documentation, be accompanied by a Mentor's Certificate. In this certificate, it is claimed that the research was conducted in accordance with the ethical standards for conducting the research.
2. Individual requests for approval of data collection for research purposes by students or employees of the University Department of Health Studies in Split are addressed to the Ethics Committee.

If necessary, the mentor of the final or diploma thesis can assess whether the candidate should apply to the Ethics Committee in any other case than those listed.

The structure of the request submitted to the Ethics Committee, depending on whether it is quantitative or qualitative research should contain the parts. For example, for the quantitative research project: the research objective, problems and hypotheses and method (participants, measuring instruments, research procedure, ethical aspects of research, data processing). For the qualitative research project: research objective, research questions and method (participants, data collection, research process, ethical aspects of research, data processing, validation, and reliability strategies).

Ethics Committee at the university level is a working group of experts, appointed by the Rector in February 2020. Two members of the Committee come from the University of Split, two members from outside the University of Split, and one member is a student, appointed at the suggestion of the Student Union of the University of Split. Their work is guided by the University's Code of Ethics (Sveučilište u Splitu, 2022). The University of Split has also officially adopted the European Code of Conduct for Research Integrity and translated it into Croatian: *Europski kodeks znanstvenoistraživačke* čestitosti (Sveučilište u Splitu, n.d.).

For collaborative research, such as that conducted within the SEA-EU Alliance, the research should be approved by the Ethics Committee of the University that leads the research activity. The approval must be shared with other university representatives in the study/project. In the case of the University of Split, the procedure of ethics approval is carried out by the Ethics Committee at the university level because it is a university project unless otherwise specified.

Process for research misconduct allegations at the University of Split

The University and its components do not have a separate structure or processes for RI. Allegations of research misconduct are dealt with by the Ethics Committees.

If misconduct is observed, an allegation should be made to the Ethics Committee at the faculty/department level, or at the University level if the complaint addresses the issue within the responsibility of the University.

At the faculty/department level, the procedure is initiated by a request for an opinion about research misconduct. The request cannot be anonymous and must be supported by evidence. The Ethics Committee at the faculty/department level then provides an opinion on the basis of the allegations and data. The opinion of the Ethics Committee is given to the head of the faculty/department, to the person who submitted the allegation and to the person to whom the allegation refers. The procedure is carried out in accordance with the Statute of the University of Split and the Code of Ethics of the University of Split, and in accordance with the decisions of the Ethics Committee, the procedures for subsequent activities are followed.

The complaint is submitted at the university level when misconduct is alleged to occur at the university level (the Rectorate). The opinion of the Ethics Committee of the University applies to all persons involved in the process and cannot be challenged further.

Disciplinary responsibility

Teachers and students are subject to disciplinary action for violations of their work and other work obligations and for gross damage to their reputation. Disciplinary measures and procedures are determined by acts of the component.

University of Western Brittany, France

France has three types of higher education institutions: Universities, Grandes écoles, and specialized schools (The Embassy of Good Science, n.d.). There are 113 public and 3 private higher education institutions that provide university degrees (The Embassy of Good Science, n.d.).

As far as the research infrastructure, there are 431,000 full-time researchers 27 public institutions and 34 public institutions of scientific and technological character, public industrial and commercial establishments, foundations and special institutes in France as well as 4 National Research Alliances, thematic groupings of research organizations, and higher education institutions (The Embassy of Good Science, n.d.).

Expenditure and number of grants from European Commission programs in France

The gross expenditures on research and development were €51.8 billion, which comprises 2.2% of the country's GDP. Most funding was spent in the business sector (65.41%), higher education (20.5%), government (12.5%), and private non-profit organizations (1.59%) (The Embassy of Good Science, n.d.). The number and source of the funded projects in France is presented in **Table 4**.

Table 4. The number and source of funded projects in France*

Grant source	Number of grants	Financial value of grants
H2020	7,488	€6.9 billion
ERC	878	€1.46 billion

*Source: The Embassy of Good Science (n.d.).

According to the ERC portal, the number of funded projects has increased in 2022 on 1521 (European Research Council, n.d.).

There are different bodies aimed to deal with the issues of the research ethics/research integrity in France from the strategic agenda, National Charter for RI, French Office for RI (OFIS) to Research institutions, such as universities, the National Centre for Scientific Research (CNRS), National Institute for Health and Medical Research (INSERM) and the French Agricultural Research Centre for International Development (CIRAD). Those bodies are obliged to prevent and handle misconduct cases. Main research governance, compliance and integrity strategies are presented in the **Table 5** (The Embassy of Good Science, n.d.).

Table 5. Research governance, compliance and integrity in France*

Research governance, compliance and integrity	Scope
Ministry of Higher Education and Research (Ministère de l'Enseignement Supérieur et de la Recherche, 2013)	A Strategic Agenda for Research, Technology Transfer and Innovation.
National charter for Research Integrity (French National Charter for Research Integrity, 2015)	National charter for Research Integrity was introduced in 2015 and by the end of April 2019, more than 45 research institutions signed the Charter agreeing to abide by seven principles in the field of professional ethics.

*Source: The Embassy of Good Science (n.d.).

Regarding the law and regulations of research ethics/research integrity in France, there are different bodies that are tasked by implementing them (**Table 6**).

Table 6. Bodies implementing the laws and regulations regarding research ethics/research integrity (RE/RI) in France*

Bodies for RE/RI	Scope
The French Office for Scientific Integrity (Leduc, n.d.)	Provides support to higher education and research institutions, observes the implementation of the National Charter, and contributes to the promotion of RI at the national and international level.
Ethics Committees (EUREC, 2023)	Have responsibility for decisions concerning interventional studies, the standard of care studies, medical and other health products, and further research areas.
The National Consultative Ethics Committee for Health and Life Sciences (CCNE, 2022)	Has an advisory role in dealing with ethical concerns in the community? All issues of medically assisted procreation and experiments on humans have to be addressed by the CCNE.
The National Centre for Scientific Research (CNRS, n.d.)	Conducts research, transfers research results, trains through research, and contributes to scientific policy.
The National Commission on Animal Experimentation (GIRCoR, n.d.)	Promotes good practices in breeding, care, and handling of laboratory animals.
Parliamentary Office for evaluation of scientific and technological options (Assemblée Nationale, n.d.)	Informs Parliament of scientific and technological options to make its decisions clear. It collects information, launches study programs, and carries out assessments.
The High Council on Biotechnology – Scientific Committee and Economic, Ethical and Social Committee	Advises the French government on issues relating to GMOs and other types of biotechnology.
The Parliamentary Office for Scientific and Technological Assessment (Assemblée Nationale, 2015)	Collects information launches study programs, and carries out assessments to inform Parliament of the consequences of the choice of scientific and technological options.
Council of Deontology – French Ministry of Education, Higher Education and Research (Ministère de l'Enseignement supérieur et de la Recherche n.d.)	Takes part in a network of national bodies competent in matters of deontology, ethics and integrity.

*Source: The Embassy of Good Science (n.d.).

Laws and regulations

The research ethics/research integrity training in France is provided together with other dialogues and communication channels established. Main research integrity/research ethics incentives are The High Council for Evaluation of Research; Higher Education (Hcéres) is the administrative authority responsible for the evaluation of higher education institutions, and research institutes (**Table 7**).

Table 7. Initiatives of the research ethics and research integrity (RE/RI) actions and their scope in France*

Initiative	Scope
RE/RI training	European Code of Conduct (ALLEA, 2017) French National Charter for Research Integrity (2015) Signature of Scientific Publications: Good Practices (Inserm – Institut National de la Santé et de la Recherche Médicale, 2021) Ethics and Scientific Integrity Charter of the ANR (Agence Nationale de la Recherche, 2019) Integrity and responsibility in research practices (CNRS, 2016) Scientific integrity guideline (CNRS, 2018) Guide for collecting and processing reports relating to scientific integrity
RE/RI dialogue and communication	The OFIS organizes the annual meeting of signatories of the French Charter of research deontology in which the universities and the other research institutions exchange policies, procedures and share their needs with OFIS
RE/RI incentives	The High Council for Evaluation of Research and Higher Education (Hcéres) is the administrative authority responsible for the evaluation of higher education institutions and research institutes.

*Source: The Embassy of Good Science (n.d.).

Process for ethics approval at the University of Western Brittany

University of Brest – UBO has to provide a rigorous and trustworthy scientific approach of its research activities thus meeting funding agencies and civil society's demands.

UBO has appointed a Scientific Integrity Referee, professor Claude Ferec who gets assistance from two other professors, Georges Barbier and Jacques Le Gall. They form the "Scientific Integrity Triplet" which is the first to contact (e-mail: referent-integrite-scientifique@univ-brest.fr) whenever an issue related to deontology or scientific integrity occurs.

It also has a public mission of informing and advising UBO's community on scientific integrity principles as well as promoting harmonization and mutualization of good practices in compliance with the national rules.

Bodies and processes for research integrity at the SEA-EU university member

A Non-Interventional Scientific Research Ethics Committee [CERNI in French] was set up at a regional level of "Brittany University Alliance" (AUB, 2022).

This committee is in charge of ethics and research deontology issues in non-interventional research where humans are implied in compliance with 2012-300 law of 05/03/2012 (Jardé Law) amended in the 16/06/2016 (2016-800). This Scientific Research Ethics Committee enables research teams dealing with research issues involving directly or indirectly human being excluding clinical or physically invading research to comply with ethics rules. This Committee can be contacted by the researchers for research protocols or thesis, articles submission, research grant funding, advice about ethics issues...

It also carries a public mission of ensure legislation monitoring on research on humans and data protection which can also be done on a national level with ethics committees from other universities or research organisms.

The CERNI is composed of members from all scientific domains for which issues can arise. It has a steering board chaired by UBO's research vice-president, Université de Bretagne

Sud (UBS)'s research vice-president and the National Engineering School of Brest (ENIB)'s research director.

An expert is designated to review methodology, data protection and human respect. The evaluation is sent to the Bureau to give an assessment whether positive or with minor/major modifications. Modifications are to be sent within one month before resubmission. Final assessment is given within 15 days after resubmission.

If the project falls into the interventional research scope, the CERNI transmits the case to the Human Protection Committee.

A positive evaluation of a project review by the CERNI indicated that it complies with the ethics rules.

Process for research misconduct allegations at the SEA-EU university member

The "Scientific Integrity Triplet" is the first to contact when a scientific fraud is suspected. It helps UBO's governance whenever a scientific integrity case is at stake.

University of Cadiz, Spain

In Spain, there are 75 universities of which 50 of them are public and 25 are private ones. A detailed list of all the universities can be found in The Embassy of Good Science (n.d.).

In 2019 there were 135,331 full-time researchers in Spain, together with 20 research institutes out of which 51 are joint centres with other institutions, primarily universities. There are also 8 centres functioning as research support units that provide technical and administrative support to two or more institutes.

Expenditure and number of grants from European Commission programs in Spain

In 2019, the gross expenditures on research and development were €15.572 million, which comprises 1.25% of the country's GDP. Spain had 8.137 signed grants receiving €5.82 billion in H2020 and 491 ERC signed grants receiving €664.8 million in H2020 (The Embassy of Good Science, n.d.).

Bodies responsible for research ethics/research integrity are the Ethics Committee of the Spanish National Research Council (CSIC, 2013), the Spanish Research Ethics Committee (CEEI), the National Commission on Assisted Human Reproduction (Royal Decree 42/2010 of 15 January, 2010) and the Commission for the Donation and Use of Human Cells and Tissues (The Embassy of Good Science, n.d.).

Law and regulations

Existing law and regulations in the Spain that refer to the research ethics and research integrity are presented in **Table 8**.

Table 8. Laws and regulations regarding research ethics and research integrity in Spain*

General State Administration and the Regional Administrations – The Spanish Strategy on Science, Technology and Innovation 2013–2020 (Ministerio de Economía y Competitividad, 2013)	**The Spanish Strategy on Science, Technology and Innovation 2013–2020**

*Source: The Embassy of Good Science (n.d.).

The scope of the bodies for research ethics/research integrity in Spain are presented below in the **Table 9**.

Table 9. Body for research ethics and research integrity (RE/RI) and scope of their action*

Bodies for research ethics/research integrity	Scope
Ethics Committee of the Spanish National Research Council – CSIC (ENRIO, n.d.)	Investigates, trains and promotes research integrity. It also issues report and formulates recommendations about ethical and deontological principles related to research activity.
The Spanish Research Ethics Committee (Ministerio di Ciencia e Innovacion, 2022)	
The National Commission on Assisted Human Reproduction (The Embassy of Good Science, n.d.)	Guides the use of assisted human reproduction techniques and collaborates with public administrations about this matter.
The Commission for the Donation and Use of Human Cells and Tissues (Boletín Oficial del Estado, 2010)	Advises and guides research with biological samples of human embryonic nature and contributes to the updating and dissemination of scientific and technical knowledge in this matter.

*Source: The Embassy of Good Science (n.d.).

Ethics Committee of the Spanish National Research Council, The Research Ethics Committee of the Carlos III Health Institute (Ministerio di Ciencia e Innovacion, 2022), The Spanish Bioethics Committee, The National Commission on Assisted Human Reproduction, The Commission for the Donation and Use of Human Cells and Tissues are bodies that ordines' the lay regarding Research ethics and research integrity in Spain.

There is no mandate for RI training in Spain and RE/RI dialogue and communication is about 56%. Spain provides Research and Development tax relief through a hybrid tax credit and social security contributions exemption for qualified research staff. Initiatives of the related actions are presented in **Table 10**.

Table 10. Initiatives of the research ethics/research integrity (RE/RI) actions and their scope in Spain*

Initiative	Scope
RI/RE training	There is no mandate for RI training but some universities and institutions have integrated a module about RI in their existing program about research ethics (the Autonomous University of Madrid, University of Barcelona, University of Oviedo, and the National University of Distance Education)
RI/RE dialogue and communication	In a Knowledge Transfer study 2010–2012, Spain's positioning is about average (56%). Spain is one of the countries with a low level of innovation and weak knowledge translation policies
RI/RE incentives	Spain provides Research and Development tax relief through a hybrid tax credit and social security contributions exemption for qualified research staff. Both of these incentives are mutually exclusive in their use except for innovative small and medium-sized enterprises

*Source: The Embassy of Good Science (n.d.).

Process for ethics approval at the University of Cadiz

The regulations contained in different calls for proposals for research funding require that projects involving research involving human subjects, the use of personal data, biological samples of human origin, animal experimentation, biological agents, or the use of genetically modified organisms not only comply with the requirements established in each case by law but also have the express authorization of the Ethics Committee of the Centre where the research is to be carried out.

The University of Cadiz, as a Public Body for Research and Teaching, is aware of its duty and responsibility to society and, consequently and by article 189 of its Statutes, it constitutes a Bioethics Committee (Universidad de Cádiz, n.d.-a), which responds quickly and effectively to current needs or future needs to protect the fundamental rights of people, animal welfare and the environment.

The Committee extends its competence to the field of research using personal data for the purposes set out in Article 1(1)(d), which are subject to confidential processing because they affect the rights and freedoms of individuals, interests linked to the defence and protection of the environment or other constitutionally and legally protected assets.

Committee authorised by the Junta de Andalucía for animal research by the Junta de Andalucía

Resolution of 9 September 2013, of the Directorate General of Agricultural and Livestock Production, authorizing the Ethical Committee for Animal Experimentation of the University of Cadiz as the body authorized to evaluate animal experimentation projects (Universidad de Cádiz, n.d.-b).

Bodies and processes for research integrity at the SEA-EU university member.

At the University there is a Bio-Ethics Committee and also here are members associated by the fields.

There is also publicly available information at the university website that is dedicated to plagiarism.

University of Gdansk, Poland

According to data sourced from the POL-on Integrated Information Network on Science and Higher Education, administered by the Information Processing Centre – National Research Institute (Radon, n.d.), as of 31 December 2021, there were 426 higher education institutions in Poland, including 131 public higher education institutions, 278 non-public higher education institutions, of which 57 institutions were in liquidation, and 17 religious higher education institutions. A crucial component of the scientific sector in Poland are research and scientific institutes. This group comprises the following types of entities (Research in Poland, n.d.): scientific institutes of the Polish Academy of Sciences (n=77), research institutes (n=76), Łukasiewicz Research Network institutes (n=36), international

research institutes (n=2), other scientific institutions (n=54). In 2020 the R&D personnel amounted to 283.4 thousand of persons, i.e. 4.6% more than in the previous year. The largest share in the structure of this personnel belonged to people involved in R&D in the higher education sector (48.7% of R&D personnel in Poland, i.e. 3.3 percentage points less than in 2019). The actual involvement of R&D personnel in scientific research and experimental development was 173.4 thousand in full-time equivalents. In Poland, one person involved in the research and development projects has spent an average of 61.2% of their working time on these works (Główny Urząd Statystyczny, 2020).

The Polish Roadmap of Research Infrastructure is a list of undertakings of strategic importance to the development of Polish science and its competitiveness. It includes infrastructures with the highest research potential – facilities that embrace the best scientists and innovative businesses. The 2020 update of the Map covers 70 undertakings – 40 national undertakings and 30 facilities with an international dimension: Physical sciences & engineering (23 projects), Social sciences & humanities (6 projects); Technical sciences & energy (14 projects); Earth & environmental sciences (5 projects), Medical, biological & agricultural sciences (16 projects), Digital infrastructures (6 projects) (EURAXESS Poland, n.d.).

Gross expenditure on research and development and its distribution across sectors

According to published data from the Central Statistical Office (Statista, 2022), gross domestic expenditure on research and development (GERD) in Poland in 2020 amounted to 32.4 PLN billions, increasing year-on-year by 7.0%. R&D intensity indicator (GERD/GDP) was 1.39%, up 0.07 pp on 2019. In 2020 the business enterprise sector incurred the highest intramural expenditure on R&D (BERD); they amounted to 20.4 PLN billions and accounted for 62.8% of gross domestic expenditure on R&D. More than one third of the total value of intramural expenditure on scientific research and experimental development was attributed to the higher education sector (HERD), whose expenditure amounted to 11.3 PLN billions. In the case of the government sector and private non-profit sector, were allocated to R&D, respectively 639.1 PLN millions (GOVERD) and 79.5 PLN millions (PNPERD) (Statistics Poland, 2022). Data available on the European Structural & Investment Funds portal, reported that Poland through 7 national and 17 regional programmes, benefitted from EU funding of EUR 91.3 billion under the 2014–2020 ESIF programmes (as of January 2022). According to the Cohesion Open Data Platform his represented an average of 2 400 euro per person in the 2014 population (European Commission, n.d.-a). Horizon 2020 is the largest research and innovation funding programme in the history of the European Union. Its budget for 2014–2020 is almost 80 billion euros. New statistics on the previous 323 programme competitions have been published by the National Contact Point for EU Research Programs. After 323 competitions, Poland has received grants in the total amount of EUR 218.44 million from the Horizon 2020 Framework Programme and is involved in the implementation of 695 projects (NAWA – Polish National Agency for Academic Exchange, n.d.-b).

The European Research Council, set up by the European Union in 2007, is the premier European funding organisation for excellent frontier research. It funds creative researchers of any nationality and age, to run projects based across Europe. The ERC offers 4 main grant schemes: Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants.

So far ERC has funded in Poland 54 projects with a total budget of over 93 million euros (European Research Council, n.d.).

Research and development activities are performed in Poland by public and private sector institutions. However, most of such activities are carried out in the public sector. Key actors are universities, research, and scientific institutes, as well as commercial and non-profit companies of different sizes. Funding for research comes mainly from the state budget in the form of statutory funding and grants. The former is mainly allocated to the institutions by the Ministry of Education and Science, depending on the results of the national evaluation carried out every 4 years. Grants are offered through open calls by agencies subordinate to the Minister of Science and by other non-governmental institutions and private sector. R&D units are also largely supported by the European Structural Funds and Framework Programmes such as Horizon 2020 (2014–2020) or Horizon Europe (2021–2027).

Bodies for research ethics and research integrity and scope of their action

Several institutions located in Poland and abroad support research and development activities and help the government and its agencies to create a research and innovation strategy. Apart from the national bodies, there are organisations that represent interests of their members to the state and local government authorities and to the other organisations operating in research and development sector (EURAXESS Poland, n.d.): Ministry of Education and Science, Polish Agency for Enterprise Development (PARP), National Centre for Research and Development – National Contact Point for Research Programmes of the European Union, Conference of Rectors of Academic Schools in Poland (CRASP), Polish Academy of Sciences (PAS), Main Council of the Research Institutes (RGIB), Polish Young Academy, Business & Science Poland (BSP), Polish Science Contact Agency (PolSCA).

Organizations that play an important role in the functioning of the University of Gdańsk as an entity conducting research activities or that are important for Polish science are included in **Table 11**.

Organization of research ethics committees

The Code of Ethics for Research Workers

The “Code of Ethics for Research Workers” was developed by the Science Ethics Commission operating at the Polish Academy of Sciences, whose main role is to express opinions on cases of violations of the principles of ethics in science by employees of universities, scientific units of the Academy and research institutes, as well as to conduct activities aimed at disseminating standards of scientific research integrity. It indicates recommendations for dealing with scientific data, research procedures, publishing practices, reviewing and giving opinions on papers. The latest Code of Ethics for Researchers was developed by the Science Ethics Commission (Commission for Research Integrity) and adopted by the General Assembly of the Polish Academy of Sciences on 25 June 2020 (Kancelaria Sejmu, 2022).

Table 11. Overview of the responsible bodies for research activities in Poland*

National Centre for Research and Development in Poland (National Centre for Research and Development in Poland, n.d.)	NCBR is the main funder of research, development and innovation in Poland. The agency helps in creating and deploying innovative technologies and solutions based on scientific research and experimental development, strengthening the collaboration between business and science. Since 2007, NCBR has supported over 13,000 projects, 6,700 enterprises and 5,000 institutions, channelling over €14 billion into Poland's R&D ecosystem. It cooperates with 13,500 Polish experts and 1,500 experts from all over the world. NCBR is also a National Contact Point for Horizon Europe and provides extensive training and consultation services for Polish applicants (National Centre for Research and Development in Poland, n.d.).
National Science Centre (National Science Centre in Poland, n.d.)	NCN is a government agency, supervised by the Ministry of Science and Higher Education. It funds projects in Arts, Humanities and Social Sciences, Life Sciences and Physical Sciences and Engineering. The goals of NCN are: 1. supporting excellent research projects in all fields of science and humanities; 2. funding doctoral scholarships and post-doctoral internships; 3. financing research projects carried out by experienced researchers aimed at implementing pioneering research important for the development of science; 4. inspiring international cooperation in basic research; 5. supervising the implementation of the awarded research projects; 6. supporting and developing the scientific careers of pre-doctoral and doctoral researchers about to embark on a career in research (National Science Centre in Poland, n.d.).
Polish Academy of Sciences (PAN, n.d.)	PAN is the most significant scientific institution in Poland. Its mission is to work comprehensively to further the advancement of science, in the service of society and for the enrichment of Poland's national culture, while adhering to the highest standards of research quality and ethical norms. The Academy is an elected body of scholars, including national members (ordinary and corresponding members) and also foreign members (Polish Academy of Sciences, n.d.).
Polish National Agency for Academic Exchange (NAWA)	NAWA was set up to coordinate state activities driving the process of internationalization of Polish academic and research institutions. The mission of it is to foster the (NAWA – Polish National Agency for Academic Exchange. n.d.-b).
Platform "Research in Poland"	The researchinpoland.org website, launched by NAWA, is available in English and dedicated to foreign scientists and PhD candidates. The aim of the website is to fulfil three key informational and promotional requirements: • provide foreign researchers with key information concerning the Polish system of higher education and the organization of their stay in Poland; • equip the researchers interested in pursuing their scientific careers in Poland with tools such as search engines enabling them to find: jobs/projects, grants, scientific events, so that they can find what is most relevant for them; • promote the achievements of Polish science and Polish scientists through the success story component (Research in Poland, n.d.).
Łukasiewicz Research Network	Łukasiewicz is part of the government's innovation support system and operates in a planned and coordinated manner, in research groups. They follow the research directions pointed by the Council of the Łukasiewicz Center, identified as key to achieving the objectives of the Strategy for Responsible Development. These include: smart and clean mobility, digital transformation, health, sustainable economy and energy. Łukasiewicz develops research programs that channel the work of scientists into areas strategic to the development of the economy and society (NAWA – Polish National Agency for Academic Exchange, n.d.-a).
The Medical Research Agency (ABM – Agencja Badań Medycznych, n.d.)	MRA was founded in order to improve the use of potential for development of medical research and health sciences, particularly in the scope of non-commercial clinical research. The main goals of non-commercial clinical research development shall include searching for new methods of treatment in the most pressing areas of medicine: oncology and cardiology, and also in the area of rare diseases, as often they are outside the area of interest of private companies (ABM – Agencja Badań Medycznych, n.d.)
The Fahrenheit Union of Universities	It was established in September 2020 upon the joint request of the Rectors of the Medical University of Gdańsk, Gdańsk University of Technology and the University of Gdańsk. The most important task of the Union is the best possible use of the resources and potential of the three universities forming the Union. Its activities focus on the development of solutions supporting joint research and development work, as well as the recommendations pertaining to the consolidation or creation of new, intercollegiate doctoral schools (Fahrenheit Universities in Gdańsk, n.d.).
Copernicus Academy	The tasks of the Academy include (Kancelaria Sejmu, 2022): 1) financing scientific research, including awarding: a) Copernican Scholarships, b) Nicolaus Copernicus Grants; 2) supporting the Nicolaus Copernicus School; 3) granting Copernican Awards; 4) appointment of Ambassadors of the Copernicus Academy and granting financial support for the tasks performed by them; 5) organisation of the World Copernican Congress; 6) preparation and organisation of conferences, symposia and seminars; 7) international cooperation.

*Source: Authors.

The Code of the National Science Centre on Research Integrity and Applying for Research Funding

On 11 May 2016, the Council of the National Science Centre introduced the Code of the National Science Centre on Research Integrity and Applying for Research Financing by way of Resolution No 39/2016. The Code consists of three parts. The first one contains a discussion of possible methods of applying good practices and principles of integrity to scientific research, starting from the stage of planning, to implementation, to the publication of results. The second chapter is dedicated to the issues of teaching, training and supervision in connection with research integrity rules. The third chapter deals with the lack of research integrity and possible forms of abuse in this respect, as well as sanctions the Centre may impose on the researcher and the institution if the lack of research integrity is found in the application or at the subsequent stages of implementation of the project, including the presentation of research results (National Science Centre, 2016).

Laws and regulations

The structure and basis of operation within the research system in Poland are defined in the Higher Education and Science Law, known as the Constitution for Science, in short Law 2.0 (introduced in October 2018). The Law enforces significant changes to the science system, among others it creates better conditions for scientific and didactic excellence, ensures sustainable development of academic centres across the country, introduces doctoral schools and gives universities appropriate tools necessary for effective management. Data on Polish science and higher education is collected by an integrated POL-on System created in 2011 with an objective to exert genuine influence on the effectiveness of public spending on science and education (EURAXESS Poland, n.d.).

Measures to promote good scientific practices and open science

The “Initiative of Excellence – Research University” (IDUB) programme is a key element of the Law on Higher Education and Science. The priority of the programme is to identify and support universities that will strive to achieve the status of research universities and will be able to successfully compete with the best academic centres in Europe and around the world. The programme gives the winners the possibility to raise the quality of scientific activity and education and, consequently, increase the international significance of the university’s activity.

In 2019, the Ministry of Science and Higher Education held the first competition under this programme. As a result, ten universities, out of the twenty eligible, have been guaranteed an annual funding increase of ten per cent of the 2019 subvention in the period from 2020 to 2026 to implement the development plans included in the competition applications. The remaining participating universities have been receiving a subsidy increased by two per cent (Research in Poland, n.d.).

Process for ethics approval at the University of Gdansk

Pursuant to the Rector's Order No. 92/R/21 of 21 June 2021, the University of Gdańsk has a Research Ethics Committee composed of a dozen members and chaired by the Vice-Rector for Research.

The Committee's tasks include in particular: ensuring that scientific research complies with high ethical standards, supporting researchers in resolving ethical dilemmas related to the planning and conduct of scientific research, giving opinions or consents on research where human impact is planned.

In performing its tasks, the Committee shall consider the principles contained in the Code of Ethics for Academic Teachers of the University of Gdańsk established by Resolution No. 40/07 of the Senate of the University of Gdańsk of 28 June 2007 (as amended), as well as – complementarily – in the Code of Ethics for a Researcher developed by the Commission for Ethics in Science and adopted by the General Assembly of the Polish Academy of Sciences on 1 December 2016 (as amended).

In giving its opinion or consent to research involving human subjects, the Committee shall further take into account the principles contained in:

1) The Universal Declaration on Bioethics and Human Rights adopted on 11 November 1997;
2) The Guide for members of ethics committees for scientific research of 7 February 2011 issued by the Steering Committee on Bioethics of the Council of Europe;
3) Principles of the Council of the National Science Centre for Research Involving Human Subjects dated 3 March 2016.

Bodies and processes for research integrity at the SEA-EU university member

The University of Gdańsk has an ombudsperson for scientific integrity, as well as a disciplinary spokesperson and disciplinary committees.

The ombudsperson for scientific integrity is appointed by the Rector – in accordance with § 37b of the Statute of the University of Gdańsk (Uniwersytet Gdański, 2020), his/her tasks include in particular:

1) taking action to shape and consolidate high standards of scientific integrity at the University of Gdańsk;
2) developing and promoting good scientific practice;
3) clarifying doubts concerning the scientific integrity of employees and doctoral students of the University;
4) requesting the disciplinary spokesperson to act in the event of a justified suspicion of scientific dishonesty of employees or doctoral students of the University;

5) drafting opinions on scientific integrity issues at the request of the bodies of the University.

In turn, the function of the disciplinary spokesperson is set out in the Law on Higher Education and Science (Article 277 et seq.). Disciplinary spokespersons in a higher education institution are appointed by the Rector from among academic staff holding at least a doctoral degree. The disciplinary spokesperson shall be competent for the disciplinary liability of academic staff.

The disciplinary spokesperson shall initiate an ex officio enquiry for an act involving:

1) appropriating the authorship or misrepresenting the authorship of the whole or part of another person's work or artistic performance;
2) distributing, without the name or pseudonym of the author, another person's work in the original version or as an adaptation;
3) distributing, without the name or pseudonym of the author, another person's artistic performance or publicly distorting such a work, artistic performance, phonogram, videogram or broadcast;
4) infringement of another's copyright or related rights in a manner other than specified in points 1–3;
5) falsification of scientific research or its results or committing other scientific fraud;
6) accepting or demanding a financial or personal benefit or the promise thereof in connection with the performance of a function or the holding of a position in a higher education institution;
7) invoking influence in a higher education institution, a public or local government institution or an organisational unit administering public funds, or persuading another person or leading them to believe that such influence exists, and undertaking to act as an intermediary in the settlement of a matter in return for a financial or personal benefit or the promise thereof;
8) the giving of, or the promise of, a financial or personal benefit in return for the intermediation in the handling of a matter in a higher education institution through influencing a decision, action or omission of a person holding a function or position in a higher education institution in connection with the performance of that function or position.

The investigation shall conclude with a request to the appropriate disciplinary committee to initiate disciplinary proceeding, a request to the Rector to inflict a penalty of a warning where the act constitutes a minor disciplinary offence or issuing a decision to discontinue the investigation.

If, in the opinion of the disciplinary spokesperson, the act has the features of an offence, the spokesperson shall inform the Rector thereof.

Following disciplinary proceedings, the disciplinary committee shall decide to: acquit the accused, renounce the infliction of the disciplinary penalty, punish the accused or discontinue the disciplinary proceedings.

The disciplinary penalties shall be: a warning, a reprimand, a reprimand with a 10%–25% reduction of basic remuneration for a period of one month to two years, deprivation of the right to act as a supervisor, reviewer or member of a commission in proceedings for the conferment of the degree of doctor, the degree of doctor habilitated and the title of professor for a period of one to five years, disqualification from holding managerial positions in higher education institutions for a period of between 6 months and 5 years, expulsion from employment in a higher education institution, expulsion from employment in a higher education institution with a ban on working in higher education institutions for a period of between 6 months and 5 years, deprivation of the right to practice the profession of academic teacher for a period of 10 years.

Varies of disciplinary sanctions

Disciplinary proceedings are two-instance. In the first instance, it is decided by the University Disciplinary Committee or the Disciplinary Committee at the General Council for Science and Higher Education (depending on the penalty requested by the spokesperson). In cases of disciplinary offenses which may constitute a breach of the principles of ethics in science, the Disciplinary Committee may request an opinion from the Ethics in Science Committee of the Polish Academy of Sciences. The Rector may suspend an academic staff member against whom criminal or disciplinary proceedings have been instituted from performing their duties if, given the gravity and credibility of the charges brought against them, it is appropriate to remove them from the performance of their duties. A decision of the disciplinary committee may be appealed against by the parties to the disciplinary committee at the Minister.

University of Malta, Malta

Six Maltese higher-education institutions meeting the following *uniRank* selection criteria:

- being chartered, licensed or accredited by the appropriate Maltese higher education-related organization
- offering at least four-year undergraduate degrees (bachelor degrees) or postgraduate degrees (master or doctoral degrees)
- delivering courses predominantly in a traditional, face-to-face, non-distance education format (uniRank, n.d.).

Detailed list of the institution: American University of Malta, Institute of Tourism Studies Malta, Malta College of Arts, Science and Technology, Middlesex University Malta, The European Graduate School and University of Malta.

In 2018, number of researchers in R&D for Malta was 1,946.5 per million people. Though Malta number of researchers in R&D fluctuated substantially in recent years, it tended to increase through 2004–2018 period ending at 1,946.5 per million people in 2018 (Knoema, n.d.).

During 2019, an increase in total expenditure on R&D activities of €5.4 million, or 7.3 per cent, was registered. The Business Enterprise sector contributed 62.0 per cent to total R&D, whereas the Higher Education and Government sectors contributed 37.0 and 1.0 per cent respectively. The R&D expenditure was primarily dedicated to Basic Research, which accounted for 51.3 per cent of total R&D in 2019, followed by Applied Research (34.4 per cent) and Experimental Development (14.3 per cent) (National Statistics Office Malta, 2021).

National R&I Monitoring Report 2019 – 2020, prepared by The Malta Council for Science & Technology (2022) reported about 0.61% gross R&D expenditure as a percentage of the GDPR. From 2012 to 2019, the GDP has been growing at an average rate of 9.7% and the actual R&D expenditure is not increasing at the same rate as the GDP. The same report mentioned number of 961 researchers working as full-time employees in 2019. In 2020 there were proposals presented to H2020 that included Maltese research organisations. Trading Economics portal reported about 0.57246% Gross expenditure on research and development in 2018 (Trading Economics, n.d.).

Expenditure and number of grants from European Commission programs in Malta

Malta, through 5 national programmes, benefitted from EU funding of EUR 1 billion under the 2014–2020 ESIF programmes (as of January 2022). This represented an average of 2.330 euro per person in the 2014 population (European Commission, 2020).

Bodies for research ethics and research integrity and scope of their action

The establishment and functions of research ethics committees. Reference is made to research ethics committees in the Data Protection Law. Concerning processing of data relating to research and statistics, the Data Protection Law states: Article 16. (2b) “in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner for the purposes of this paragraph”. The Animal Welfare Act No. XXV of 2001 (2002) also refers to ‘ethical rules and standards which may be drawn up by the Council” (Art. 33 (1), implying the existence of an animal research ethics committee).

Laws and regulations

In Malta, there are following ethics committees:

1. The Bioethics Consultative Committee. This committee is in the first instance an advisory body to the Minister of Health. Its role in research is limited to formulating guidelines to be followed by various institutes and individuals, as well as to pronounce its views on questions relating to research ethics as the need arises. It is not involved in the ethical assessment of individual research projects. Its members are appointed by the Minister for Health for the duration of one year.

2. Research Ethics Committee, Medical School University of Malta. This body was set up by the Faculty of the Medical School. It examines research projects of a biomedical nature submitted to it. Researchers however have no obligation to submit their project to this

body. It reports to the Faculty of Medicine but has no authority to supervise the research projects it has authorised.

3. Other research ethics committees. The only other research ethics committee has been set up by the Senate of the University of Malta to deal with non-biomedical issues (social sciences, psychology etc). Again, there is no legal obligation on the part of researchers to submit their research for scrutiny by this body (European Commission, 2003).

Procedures

Projects or procedures that should be submitted to ethics committees Research relating to biomedical issues should all go to a medical research ethics committee, while all other research involving human beings should go to the University Research Ethics Committee. As mentioned already, there is currently no obligation on the part of researchers to submit their research project for approval to an ethics committee. Note, however, that research involving animals is now covered by the Animal Welfare Law which specifically requires such approval, as mentioned above (European Commission, 2003).

Health Ethics Committee

The function of the Health Ethics Committee shall be to give an opinion before a clinical trial commences on any issue requested. In preparing its opinion the Ethics Committee shall consider the various factors outlined in Regulation 7 of the Clinical Trials Regulations 2004 and including devices and interventions. The principal function of the Health Ethics Committee shall be to give an opinion on clinical trials on medicinal products and medical devices, in terms of the Maltese Clinical Trials Regulations (LN490 of 2004). To evaluate proposals for research being conducted in the health sector, including ethical and data protection aspects. The Health Ethics Committee is to carry out this responsibility in close collaboration with the Research Ethics Committee within the Faculty of Medicine and Surgery in the University of Malta and in line with the provisions of the Data Protection Law (Ministry for Health, n.d.).

Process for ethics approval at the University of Malta

Although Malta has no national document on research integrity, the University of Malta expects its students, researchers and staff to abide by its code of practice. It describes both the ethical principles and their application, with special attention to research involving human participants or animals (The Embassy of Good Science, n.d.). The University of Malta recognises its responsibility to researchers and the wider community to ensure that the highest standards of integrity and professionalism are observed in the conduct of research at the University.

University of Malta staff, students, or anyone else planning to carry out research under the auspices of the University, must complete the application on URECA (L-Università ta' Malta, 2019). The University's Research Code of Practice provides guiding principles and standards of good practice in research across all subject disciplines and areas of study at UM. At the University website, there are available Research Ethics Review Procedures that clearly describe universities' procedures (L-Università ta' Malta, 2019).

The University's Research Ethics Review Procedure lays out the procedure to be followed to review ethics in research.

Bodies and processes for research integrity at the SEA-EU university member

The University of Malta recognizes its responsibility to researchers and the wider community to ensure that the highest standards of integrity and professionalism are observed in the conduct of research at the University.

The University's Research Code of Practice provides guiding principles and standards of good practice in research across all subject disciplines and areas of study at UM.

The University's Research Ethics Review Procedures lays out the procedure to be followed to review ethics in research (L-Università ta' Malta, 2019).

Kiel University, Germany

Based on the information available at the EuroEducation.net (n.d.), there are currently 397 universities in Germany with a combined student population of approximately 2.8 million. Of these, 115 are universities or similar institutions, 217 are universities of applied sciences (in German 'Fachhochschulen'), 57 are colleges of art or music, 8 do not belong to one of these three categories. This total includes:

- 120 universities (Universitäten)
- More than 200 universities of applied sciences (Fachhochschulen/Hochschulen für angewandte Wissenschaften)
- Almost 60 art and music colleges (Kunsthochschulen/Musikhochschulen)

In addition, Germany's tertiary sector also includes either state-run or state-recognised Berufsakademien in some Länder. The Fachschulen and the Fachakademien in Bayern are also part of the tertiary sector (EuroEducation.net, n.d.).

Higher Education Institutions are either state or state-recognized institutions. In their operations, including the organization of studies and the designation and award of degrees, they are both subject to higher education legislation (HRK – Hochschulrektorenkonferenz, n.d.).

Roughly 90 percent of students in Germany study at public institutions. However, the private sector has been growing in recent years and now encompasses 150 privately-funded universities, almost 40 of which are run by churches.

Number of researchers, higher education institutions, non-university centres, and non-university organizations in Germany

According to the Research in Germany (n.d.), there are around four hundred higher education institutions, 720,000 staff in total, including 402,000 academic staff, 2.9 million students in total, including almost 412,000 international students (14.2%). Also, gross domestic expenditure on research and development (GERD) is 18.4 billion euros.

More than 1 000 public and publicly funded institutions for science, research and development are present in Germany. Over 400 research and innovation networks and clusters. 708.000 staff in R&D including 43.000 researchers. More than 45.000 patent registrations worldwide.

According to the German Research Landscape, expenditure on R&D is 104.7 billion euros or 3.1% of GDP (Research in Germany, n.d.).

Expenditure and number of grants from European Commission programs in Germany

Germany, through 2 national and 45 regional programmes, benefitted from EU funding of EUR 34 billion under the 2014–2020 ESIF programmes (as of January 2022). According to the Cohesion Open Data Platform, this represented an average of 420 euro per person in the 2014 population (European Commission, n.d.-a). There are 200 ERC projects funded according to the ERC portal (European Research Council, n.d.).

When it comes to the other funding possibilities – it is important to mentioned that over 30.000 Projects Funded in 2020 by the DFG – The Deutsche Forschungsgemeinschaft (2019) funded more than 31.100 new and ongoing projects with a funding volume of €3.3 billion (Deutsche Forschungsgemeinschaft, 2022).

Body for research ethics/research integrity and scope of their action

In Germany researchers are required by law to obtain ethical approval for studies with human participants (ENRIO, 2019).

Germany has a total of 53 research ethics committees, 33 attached to Faculties of Medicine/Universities, 17 attached to Medical Associations (“Ärztekammern”) in the States and 3 attached to States governments. These RECs are the only legally competent ethics committees to assess all kind of biomedical research including drug research. The legal competence of the 3 RECs attached to States governments is restricted to drug research and to research on medicinal devices. These RECs are established in conformity with States law. The Federal Republic has no competence for that establishment.

Around 55% of all projects in the field of biomedical research are drug research, whereas around 45 are attributed to other types of biomedical research. Different legal regulations are in force for both of these groups.

By the 12th Novel of the Federal Drug Law (“Bundesarzneimittelgesetz”) for the implementation of EU-Directive 2001/20/EC (4th of August 2004) was introduced that a drug trial may only be begun with the favourable opinion of a REC established in conformity with States law (“Landesrecht”) and with the approval given by the competent Federal authority European Network of Research Ethics Committees (EUREC, n.d.).

National Level

a.) The National Council for Ethics: http://www.ethikrat.org/ (“Deutscher Ethikrat”), as established by the legislation of the “Deutscher Bundestag” on April 26, 2007 may give recommendations that are not binding.

b.) There is the Central Ethics Committee of the German Medical Association ("Zentrale Ethikkommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten bei der Bundesärztekammer [ZEKO]") which gives opinions on general ethical issues and which may give advice to the Ethics Committees of the Medical Associations at their request. This advice is not binding on these committees (EUREC, n.d.).

Networking between RECs

In 1980 a group of German academics interested in research ethics formed a working group to discuss emerging issues of clinical research and the ethical review process. This working group initiated a forum for the exchange of information and harmonization for the work of ethics committees, as established by the Faculties of Medicine and the Medical Associations in the German States ("Bundesländer") since the late seventies – "Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland" ("Permanent Working Party of Research Ethics Committees in Germany") (AKEK – Arbeitskreis für Klinische Ethik-Komitees, n.d.). Up to now, there is no National Ethics Committee for medical research in Germany, therefore this group is accepted as an important consultancy for the public, governments and parliaments.

The Working Party organizes semi-annual meetings and training for REC members, specifically for persons invited to become a REC member. Training is performed on a national and on a regional level (EUREC, n.d.).

Laws and regulations

Germany has a national institutional structure for research integrity: a national research ombudsman (the German Research Ombudsman) that serves as a nationwide mediator in conflicts on correctable suspected research misconduct. The formation of this national research ombudsman complements the network of the local ombudspersons in research institutions, whereby scholars and researchers are free to submit inquiries to the local bodies or to the national research ombudsman. There is no (legal) obligation to seek the national research ombudsman in cases of suspected research misconduct. Besides the national research ombudsman, there are other organisations in Germany operating nationwide, such as the Deutsche Forschungsgemeinschaft (Deutsche Forschungsgemeinschaft, 2019), having investigatory and decision-making authority in research misconduct cases within its scope (i.e., misconduct related to research proposals and/or DFG-funded research projects). The DFG provides more detailed information on guidelines and processes related to research integrity on their website (see here and here). Apart from these structures, non-university research institutions (Fraunhofer, Helmholtz Association, Leibniz Association, Max Planck Society) have also appointed ombudspersons within their institutes, who may be contacted in cases of suspected research misconduct. Moreover, in 2011, an initiative in promoting research integrity and preventing research misconduct was taken by two scientists and a mediator who worked inside the national and a local office dealing with GSP and misconduct who founded Team Scientific Integrity (Team Scilnt). This, after they earlier had published the "Curriculum 'Good Scientific Practice' for

Courses in Science and Medicine" on behalf and in cooperation with the German National Ombudsman and supported by DFG. At present, the team includes more (associate) members who conduct workshops and trainings, give presentations on good scientific practice and research integrity, and advise research institutions that wish to implement or revise regulations or procedures concerning good scientific practice and research integrity. The team also counsels' individuals on protecting their scientific integrity. Further than that, the team develops curricula and teaching materials for courses, workshops, presentations and trainings. Research on the prevalence of misconduct and the knowledge of researchers about good scientific practice and research integrity is an additional field of activity (ENRIO, 2019).

Initiatives of the research ethics/research integrity actions and their scope in Germany

With the assistance of the German Research Foundation, the 'Research Ombudsman' committee has developed a curriculum for good scientific practice for all academic disciplines (Deutsche Forschungsgemeinschaft, 2019). This curriculum can be used for classes on good research practice at universities and research institutions, in Research Training Groups and within structured doctoral training. The curriculum offers two-part learning and training opportunities: the first part concentrates on case studies and the second part can be used within the framework of furthering academic qualifications. Since 2012, the DFG has also funded a workshop for local ombudspersons at universities and research institutions on the topic of mediation and conflict management. This workshop provides ombudspersons with specific support for their work and offers them a forum for discussing conflicts and how to resolve them (Science Europe, 2016).

Process for ethics approval at the Kiel University

As a place of research, teaching and the promotion of early career researchers, Kiel University is committed to upholding professional scientific standards and to ensuring that ethical research guidelines are established and adhered to.

All scientific work is based on the principles of good scientific practice. At the CAU, scientists receive support and advice on this key topic, not only to avoid personal misconduct, but also to recognise and adequately address misconduct when supervising students and doctoral researchers.

Kiel University, together with the organisations for promoting early career researchers, wants to promote and ensure basic principles of honesty and fairness in science. The University Senate therefore adopted new guidelines for safeguarding good scientific practice at its meeting on 10 May 2017. The current guidelines are based on the recommendations of the Committee on "Professional Self-Regulation in Science" of the German Research Foundation, and implement appropriate procedures to deal with suspicions of scientific misconduct.

Accompanying documents:

- CAU guidelines for good scientific practice

- Annex 1 – Catalogue of possible sanctions
- Guideline for Good Scientific Practice of Deutsche Forschungsgemeinschaft (Deutsche Forschungsgemeinschaft, 2019) (in German only).

With the adoption of regulations dealing with freedom of research and research risks in 2013, Kiel University follows the guidelines and rules of the Max Planck Society. As such, the university is committed to the principles of ethically acceptable research, extending the boundaries of knowledge and serving the public interest, as well as protection of the environment (Kiel University, n.d.).

Bodies and processes for research integrity at the SEA-EU university member

CAU Ethics Committee (excluding medicine)

The CAU Ethics Committee provides support for researchers at the university on issues of research ethics, mediates in differences of opinion between researchers on relevant matters, and issues recommendations on implementing research projects.

Ethics Committee at Kiel University's Faculty of Medicine

The Ethics Committee at the Faculty of Medicine assists faculty members with advice and assessment of ethical and legal aspects of medical research on human beings, without prejudice to the responsibility of the medical doctor for the research project and its implementation (Kiel University, n.d.).

Process for research misconduct allegations at the SEA-EU university member

The approach towards certain high-risk aspects of research is subject to statutory provisions. Further information provided by the CAU on these topics can be found on the following websites/in the following documents:

- Animal welfare
- Genetic engineering
- Data protection
- Protection of intellectual property
- Occupational safety
- Radiation protection
- Nagoya Protocol

Scientific misconduct

Kiel University pursues every specific suspected case of scientific misconduct. Scientific misconduct occurs in particular when incorrect information is provided intentionally or negligently in a scientific context or intellectual property belonging to other people is infringed or their research work is sabotaged.

The Standing Committee is responsible for investigating allegations of scientific misconduct, which a member of the *Ombudsteam* notifies of it or of which it is informed directly. It carries out the preliminary investigative procedures and the formal investigative procedures (Kiel University, n.d.).

Discussion

Our analysis demonstrated significant differences but also important similarities among the members of the SEA-EU University Alliance in the capacities for research and for research ethics and integrity.

Comparison of the research infrastructure among the SEA-EU partners

In **Table 12**, there is a comparation among the SEA-EU partners when analysing all important research categories mentioned before in the text (from number of higher education institutions, number of full-time researchers to the number of grants).

The procedure for the investigation of research misconduct allegations differ among SEA-EU partner universities. For example, at Kiel University a *Standing Committee* is responsible for investigating allegations of scientific misconduct, *University Disciplinary Committee* in the case of the University of Gdansk, the *Scientific Integrity Triplet* in the case of the University of Western Brittany or *Ethics Committees* when it comes to the University of Split (at other partner universities there is no publicly available information about scientific misconduct). All the mentioned universities have developed processes and procedures on this topic. Therefore, it can be concluded that SEA-EU universities have a high level of awareness about the management of ethical procedures.

Overall, according to Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the regions (European Commission, 2022), it can be said that the share of researchers in relation to the active population is growing, when viewed globally and especially by countries whose universities are part of the SEA-EU Alliance. Also, the role of the universities is changing. Universities have a unique position at the crossroads of education, research, innovation, serving society and economy. The share of researchers shows that it has been growing for years (the observed period is from 2011), especially in the period from 2015 to 2020. These are values of 1.2073 in 2015, which grew to a value of 1.4445 in 2020. Some countries recorded a decline in the period 2017, 2018 (Ireland, Italy, Denmark, Luxembourg, Northern Macedonia, Switzerland, Iceland), but the growth continued until 2020. Among them is Malta, in the period from 2017 to 2018. For other SEA-EU countries, no individual decline was observed in the period.

When we analyse the number of the H2020 grants, especially in the SEA-EU members, it can be observed that the number of the H2020 grants follows the size of the research market. According to table provided below (**Table 13**), Germany has the largest number of the H2020 project, then Spain, France, Poland, Croatia then Malta.

Table 12. Comparison of research indicators for the SEA-EU partners

Items	Croatia (UNIST)	Spain (UCA)	Poland (UG)	France (UBO)	Germany (CAU)	Malta (UM)
GDP per capita	34,314.0 USD	40,698.7 USD	37,836.8 USD	50,541.3 USD	57,881.1 USD	48,581.5 USD
Number of HEI (public, private)	129	75	460	116	397	6
Number of full-time researchers	23,449	135,331	120,000	431,000	720,000 staff in total, 430,000 researchers	961 (2019)
Several non-university research organizations, technology centres, private companies, etc.	70	120	245	38	150 privately funded universities, almost 40 of which are run by religious organizaitons.	Two Institutes of Tourism Studies, Institute for Augustinian Studies and Discern (the Institute for Research on Signs of the Times).
% of GDP on R&D (The World Bank, 2022)	0.97 (2018)	1.24 (2018)	1.21 (2018)	2.19 (2018)	3.13 (2018)	0.57 in 2018
No of grants from EC programs and total funding in Euros	521 H2020	8137 H2020	323 H2020	7488 H2020	2 national and 45 regional programmes, benefitted from EU funding of EUR 34 billion under the 2014–2020 ESIF programmes	133 H2020
Number of ERC projects funded	8	763	51	1521	2000	0
National bodies for RI and RE and their scope	No from 2022	Existing	Existing	Existing	Existing	Existing
Organization of RI and RE at universities	Existing	Existing			Existing	Existing
Organization of research ethics committees (national, institutional, differences for different research fields, etc.	Existing at all levels	Existing at all levels			Existing at all levels	Existing at all levels
Laws and regulations regarding Research ethics and research integrity and their scope	Existing	Existing	Existing		Existing at all levels	Existing
Measures to promote good scientific practices and open science: a. RE/RI training b. RE/RI dialogue and communication c. RE/RI incentives	No RI training, but yes to the individua courses at some institutions		No RI training, but yes to the separate courses			
Process for ethics approval at the SEA-EU university member	Existing	Existing			Existing	Existing
Bodies and processes for RI at the SEA-EU university member	Existing	Existing			Existing	Existing
Process for research misconduct allegations at the SEA-EU university member	Existing	Existing			Existing	

Table 13. List of the H2020 programs funded in 2022*

Country	Signed grants	Total cost (Euro)
Croatia	181	45,791,592
France	2.623	1,234,492,528
Germany	4,758	3,756,821,282
Malta	84	17,966,380
Poland	731	228,846,942
Spain	3.064	1,443,253,112

*Source: European Commission (n.d.-b).

According to the European Research Council website in 2022 (European Research Council,, n.d.), most of the SEA-EU countries had ERC projects funded (with exception of Malta). The biggest number of projects were funded in Germany, then France, followed by Spain, Poland and Croatia.

As the number of researchers increases, so does the number of studies and publications on research, and thus the risk for challenges to research ethics and research integrity.

From the table presented above (**Table 12**) it is clear that Poland has the largest number of higher education institutions (460). The largest number of full-time researchers was recorded in France (431,000). When it comes to non-university research organizations, Poland has the largest number of higher education institutions, but other parameters besides the number should be considered, such as size, value, etc. The largest gross expenditure on RDI was recorded for Germany (3.13%), while the largest number H2020 grants recorded for France, and most ERC projects for Germany. It can be concluded that by size and economic strength, two partner countries such as France and Germany are leading in investments in science and research potential. However, some economically less powerful countries have stricter national legislation, such as Poland, as well as more precisely elaborated procedures for research ethics at the institutional level.

Despite the existence of laws and regulations regarding research ethics and research integrity, there are not many existing formal research ethics and especially research integrity training activities at the SEA-EU members, particularly for the staff. The University of Malta, which is the smallest SEA-EU partner country, with a single university, has very well-developed research ethics and research integrity framework. The partners of the SEA-EU alliance noticed the lack and the need for the organised institutional research ethics and research integrity education and independently created a new joint curriculum for graduate students. Experts held focus groups on the topic (Ursić et al., 2022), and afterwards delivered the syllabus of the course, entitled *Research Excellence*, identified modules and topics and made a call for the lecturers. After the completion of the design of the course and lecturers, an invitation to students for participation was announced. The call was shared among all partner universities and it was open to all interested attendees from February to July 2022. It was an online course with 6 modules that carried 3 ECTS points. Overall, 209 students from different partner universities enrolled in the course on Research Excellence (our unpublished data). This demonstrates that there is a strong

interest and need for training in responsible research. The goal of this study was also to create a SEA-EU landscape, within the Quality & Ethics Subcommittee, and to determine the procedure for obtaining ethical permission for research within the SEA-EU alliance. In this way, a framework applicable to all researchers operating within the alliance was set as a basis for future research in the new SEA-EU 2.0. project that started in January 2023. This activity was guided by an idea clearly described in the Ethics Manual, created by the Quality & Ethics Subcommittee (SEA-EU – The European University of the Seas, 2020), where it is indicated that the goal of the alliance is, based on legal and ethical issues identified by each partner and related to each partner's institution included in the project activities, the development of guiding principles and describing the main procedures regarding privacy, data protection, security, legal issues and ethical challenges at the partner universities.

Conclusion

Although our study analysed the universities that are relatively similar in size (around twenty thousand students), the differences are very large between the partner countries within the SEA-EU Alliance in the context of other indicators. For example, when we compare the gross expenditure on research and development or the number of researchers is taken into account, it is clear that it follows the level of the state, not the university level. Based on the information obtained from the implementation of secondary research on research and development potential, it can be concluded that all SEA-EU universities have a significant level of the research ethics culture. Spain, France and Germany have a significantly higher number of funded projects, and a significantly higher number of full-time researchers. However, the national size of the research infrastructure does not have to correlate with the implementation of research ethics and research integrity principles in the day-to-day functioning of the university.

As a recommendation for future actions, it is suggested to follow the example of good practice of creating your own educational offer in places where it is not systematically provided for. In this way, the lack of training, workshops and actions in specific support can be completed, and the educational offer can be adapted precisely to the partners for whom it is created.

Provenance: This study is part of the knowledge generated in the context of the "European University of the Seas" (SEA-EU), a consortium formed by the Universities of Cádiz (Spain), Bretagne Occidentale in Brest (France), Kiel (Germany), Gdansk (Poland), Split (Croatia), and Malta (Malta).

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