CrossGov

Coherent & Cross-compliant Ocean Governance for Delivering the EU Green Deal for European Seas

Deliverable 6.2

Strategy for Addressing Ethics and IP

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Abstract	This deliverable aims to identify the key ethical and legal requirements of the CrossGov project in relation to the involvement of research contributors (i.e. stakeholders) for workshops, surveys and interviews, and particularly the identification and recruitment thereof. It also identifies the main Intellectual Property Rights (IPR) issues to consider in CrossGov to ensure compliance with the Grant Agreement and Consortium Agreement. These are identified as copyright and database protection, including confidential information, while following the EC's "Open Science, Open Innovation, Open to the World" agenda and applying the FAIR principles to all project outputs.

Keywords	Ethics, Intellectual Property Rights, Open Science, Legal Requirements

HISTORY OF CHANGES		
Version	**Publication Date**	**Changes**

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Acronyms

Data Management Plan (DMP)

Deliverable (D)

European Commission (EC)

Plan for Dissemination, Exploitation & Communication Plan (PDEC)

General Data Protection Regulation (GDPR)

Horizon Europe (HEU)

Lead Partner (LP)

Project Partner (PP)

Open Science (OS)

Intellectual Property Rights (IPR)

1. Executive Summary

This deliverable looks at the ethical and legal requirements of the CROSSGOV project concerning.

1. **Research contributors** (i.e. stakeholders, as defined in D5.4) for questionnaires, interviews, focus groups, workshops, and observations, and particularly the identification and recruitment thereof. The practices and criteria used to identify and recruit research contributors are specifically formulated within D 5.5 (Plan for Dissemination, Exploitation, and Communication) and Tasks 5.1 and 5.2 (Definition of the common framework underlying stakeholder engagement as well as the establishment, coordination, and maintenance of the Stakeholder Forum) and more generally within all Tasks of WP5 (primarily related to co-creation, communication, dissemination and exploitation). In addition, research contributors will be provided with informed consent procedures, including an informed consent template for research participation (Annex A).

   Data processing matters are also handled concerning research participants' data management, with further information on GDPR compliance available within the Data Management Plan (DMP) (D. 6.1.).

2. **The main Intellectual Property Rights (IPR) issue in CROSSGOV** is ensuring compliance with the provisions on this in the Grant Agreement and Consortium Agreement. These are identified as copyright and database protection, including confidentiality obligations for sensitive and classified information per the definitions used in the GA (Article 13, p. 30-31) while following the EC's "Open Science, Open Innovation, Open to the World" agenda and applying the FAIR principles to all project outputs. Further information on processes ensuring IPR compliance and adherence to Open Science principles will be available in D. 6.1 (DMP) and D. 5.5 (PDEC).

2. Introduction

This report clarifies the roles and procedures for addressing the ethics and Intellectual Property Rights (IPR) in the project CROSSGOV to ensure the consistent application of legal and ethical frameworks and assist the whole partnership in the appropriate implementation of activities and the monitoring of ethical aspects and IPR protection. The strategy will be updated in M12 and M24.

CROSSGOV will use the best available knowledge to enhance the understanding on how coherence and cross-compliance of marine-related policies and legislation affect the ability to realise the goals of the EU Green Deal. The project will co-create proposals and roadmaps towards this end. The recommendations and solutions developed in CROSSGOV are reviewed by the Quality Assurance Team as laid down in the Consortium Agreement (under 6.6. of the Consortium Agreement).

Utilising the ethical self-assessment in accordance with European Horizon Europe guidelines[1], only one ethical issue was identified for the CROSSGOV project: the protection of personal data. Personal data might be collected when engaging with stakeholders through questionnaires, interviews, focus groups workshops, or observations, as well as for online applications of dedicated CROSSGOV activities.

This document also addresses CROSSGOV's general approach to managing IPR. CROSSGOV will follow the EC's "Open Science, Open Innovation, Open to the World" agenda and apply the FAIR principles to all project outputs, as well as to the collected primary data as described in D6.1 (DMP). As stated in DG Research & Innovation's study on Open Science (OS) and Intellectual Property Rights (2022)[2], the OS paradigm poses new challenges to IPR. Here, we address the issue in general, while the deliverables D. 6.1 (DMP) and D. 5.5 (PDEC) will address the concrete IPR issues to be considered when applying the OS agenda in relation to the management of primary data and exploitation and dissemination of results.

3. Ethical principles under Horizon Europe

Ethics is an integral part of research projects underlined by the European Commission (EC), specifically under Horizon Europe (HEU) research projects. The core of the ethical dilemma in research projects is to find a balance between two (or more) contradicting values. Though there are several absolute rules and regulations, the big challenge of ethics is judgement. The CROSSGOV project sees ethical compliance as pivotal to achieving research excellence. This can be done by respecting the legal framework and using the legal framework and established ethical principles as a means to enhance the quality of the research. We will follow existing EU, international and national guidelines. The HEU ethical requirements are anchored in the HE Framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)[3]. In Article 19 (1) of the regulation, it is stated that:

> *"Actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the*

[1] Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

[2] Available at: https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/open-science-and-intellectual-property-rights_en

[3] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0695&from=EN

Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols."

CROSSGOV follows, therefore, the ethical principles that are stated in this article and how they are applicable in the context of humans used in research:

- The principle of proportionality;
- The right to privacy;
- The right to protection of personal data;
- The right to physical and mental integrity of a person;
- The right to non-discrimination;
- The need to ensure high levels of human health protection.

4. Ethics self-assessment

Ethical dimension of the objectives, methodology and likely impact

The ethical dimensions of CROSSGOV's objectives, methodology and likely impact are in line with the fundamental ethical principles found in the Nuremberg Code, European Textbook on Ethics in Research, and the EC Ethics Appraisal Procedure. CROSSGOV is conducted in a participatory manner, with consented stakeholder interactions taking place in several project activities. Following the fundamental ethical principles, CROSSGOV collects personal data from research participants to form stakeholder repositories, e.g., to disseminate the e-newsletter, and uses stakeholders' input to co-create recommendations and roadmaps. CROSSGOV uses the best available knowledge to develop policy recommendations while ensuring compliance with fundamental ethical principles.

Compliance with ethical principles and relevant legislation

The CROSSGOV Core Group, made up of representatives from all project partners, will ensure compliance with fundamental ethical principles. The Core Group will monitor ethical aspects throughout the project implementation, including the 'do no significant harm' principle, and Intellectual Property (IP) rights protection. The Core Group will ensure, when needed, that local/national ethics review obligations are followed regarding survey designs, briefing materials, and project deliverables from an ethical perspective following the fundamental principles mentioned above. If needed, participants will establish Joint Processing Responsibility Agreements. CROSSGOV develops a secured Stakeholder Repository with individual access rights and assigns Stakeholder Interlocutors to ensure clear responsibilities for handling and protecting personal data and adherence to GDPR and other relevant laws. An Informed Consent form is developed and used to inform and obtain the consent of each person participating in the project stakeholder activities (see ANNEX A), i.e. in case of interviews, interactive events, webinars, and surveys. In addition, a Stakeholder Mobilization Charter (D5.4), which is an integral part of the overall project concept, will be signed by the stakeholders who will participate in the co-creation process for project outputs. CROSSGOV uses a secure management system serving and online repository for internal documents with individual access rights, in line with its DMP.

5. Intellectual Property Rights under Horizon Europe

IPR under Horizon Europe is set out in the Grant Agreement art. 16 and its Annex 5 (Specific Rules). They are further elaborated in the Consortium Agreement, e.g., based on the DESCA template. These agreements define the ownership of and access rights to results, as well as

the rules governing joint ownership, exploitation and dissemination of results, confidentiality, access rights to the existing background, and Open Science.

Based on the DG R&I's report study on Open Science and Intellectual Property Rights (2022)[4], considerations should always be made regarding how to balance OS and IPR:

- The concrete application of IPR and OS principles in relation to exploitation and dissemination of results, i.e., this is included in the PDEC (D.5.5)
- The concrete application of IPR in relation to the FAIR principles (findability, accessibility, interoperability, and reusability of data) is included in the DMP (D6.1). There should be a defined process for checking the validity of the rightsholder's consent or whether an exception/limitation applies.

6. Consistent application of ethical principles and IPR framework

The Task 6.3 lead will ensure consistent application of the legal and ethical frameworks referenced in this document. Within the ramifications of the Core Group, consisting of representatives of all partners, task 6.3 lead will assist the whole partnership in appropriately implementing activities and monitoring ethical aspects, incl. the 'do no significant harm' principle and IPR protection. The Core Group members will review documents, tasks, and deliverables in case any doubt occurs. As soon as any ethical or IPR-related question arises beyond the identified issues Task 6.3 lead (s.Pro, Data and knowledge management), supported by the Project coordinator (NIVA), will propose the issue to be included on the Core Group meeting agenda and ensures careful handling of the matter.

7. Implementing HEU ethical principles in CROSSGOV

During the CROSSGOV project, questionnaires, interviews, focus groups, workshops and observations with several stakeholders will be conducted. Participation thereof will be entirely voluntary. An informed consent procedure will be used to inform participants of the voluntary nature of their involvement, project aims, use of data, and data protection regulation and implications of the research participation This includes the right to have data erased and terminated, and a contact person they can turn to for additional information or complaints, in accordance with Art. 14 of the GA. This chapter describes the procedures and criteria that will be used to identify/recruit research participants with reference to the relevant HEU ethical principles, the informed consent procedure and the data and sampling collection of research participants.

Ethical principles in context

Ethical principles under Horizon Europe can be applied to the context of research participation:

- The principle of proportionality means that cause and effect or action and consequences should be proportional. Questions posed during interviews, focus groups, workshops, as well as in questionnaires should be proportionate to the project aims;
- The right to privacy means the absence of public attention. Information collected during interviews and surveys will be treated confidentially;

[4] Available at: https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/open-science-and-intellectual-property-rights_en

- The right to protection of personal data. Resulting data from interviews, surveys and workshops will be protected and stored securely in compliance with the latest GPDR 2016/697, which is further specified in D 6.1 (DMP);
- The right to physical and mental integrity of a person. No physical or psychological pressure will be applied in any form during the recruitment procedure and the informed consent procedure;
- The right to non-discrimination: No discrimination during the identification and recruitment of research participants will occur, meaning no discrimination based on colour, race, gender, religion, political preference, age, nationality or marital status. The CROSSGOV consortium has an international character with partners with headquarters in six different countries, and people from many nationalities are represented within the consortium;
- The need to ensure high levels of human health protection: CROSSGOV ensures that research participants will only participate in interviews, focus groups, and workshops under high levels of human health protection;
- Gender dimension is an integral part of the empirical research. Representation and equal influence of men and women in policy discussions and decisions is key to ensure representativity and legitimacy of outcomes. CROSSGOV will ensure a gender balance in i) the selection of participants for interviews, focus groups, workshops, questionnaires, and in general, for all the co-creation activities (D5.4); ii) the selection of stakeholder representatives to be invited to CrossGov events; and iii) the continuous monitoring of gender-related factors and potential issues in the case studies. Should the research reveal that there are striking gender related issues in the marine policy processes observed, the coordinator will initiate a dialogue on this matter with the EU project advisor.

The above principles will be adhered to throughout the CROSSGOV project and applied in the communication and dissemination activities, recruitment and building of the CROSSGOV Stakeholder Forum, as well as the identification, recruitment, data gathering, and processing of survey and workshop participants. They will be addressed in the specific contexts of all Deliverables of WP 5 as well as D 4.1 (Interactive roadmap)

Identification and recruitment of research participants

The identification and recruitment of research participants for questionnaires, interviews, focus groups, and workshops are further elaborated upon within the efforts of all WPs, in accordance with the concept and animation of the Stakeholder Forum (Tasks 5.1 and 5.2).

In general, following a sound methodological approach of stakeholder mapping (D5.4) participants are recruited from existing networks and approached by the Task leads and co-leads of each WP. Such networks include the existing scientific and professional connections, working groups, and initiatives with which CROSSGOV partners and the consortium is involved. Requests for research participants may also be communicated through the project website and the project newsletter, considering the principles established for the Stakeholder Forum to engage with and utilise the community interested in the project's developments.

When identifying and recruiting research participants (i.e. stakeholders), all partners of the CROSSGOV project will comply with the ethical principles. Personalised data from any research participants will not be used, and any concerns towards personal information protection will be nullified.

Data collection and data protection

This paragraph describes the principles set out in the GDPR and how the CROSSGOV project adopts protection measures to assure fair, adequate, and informed research participation.

For data collection during questionnaires, interviews, focus groups, workshops, and observations, CROSSGOV complies with the GDPR 2016/697[5]. In Article 4(1) it is stated that personal data means "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person." In Article 4(2) it is stated that processing means "any operation or set of operations which is performed on personal data or sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction." Each task involving a collection of personal data will comply with these provisions.

According to the EC's guidance on Ethics and data protection (2021)[6], data protection should be included by design and default in the context of research and development by applying the following measures when relevant:

- Pseudonymisation and anonymisation of personal data;
- data minimisation;
- applied cryptography (e.g. encryption and hashing);
- using data-protection-focused service providers and storage platforms; and
- arrangements that enable data subjects to exercise their fundamental rights (e.g. as regards direct access to their personal data and consent to its use or transfer).

The above considerations can be translated to data protection measures described below, which will be followed and applied where possible.

7.1 Personal Data

Personal data collected for the CROSSGOV project will only be stored, analysed and used anonymously, while retaining identifying keys. Personal data will not be made public and will have restrictions for usage (i.e., only within the project and for the defined tasks).

This document focuses on the processes related to the involvement of stakeholders in research. Further specification of the GDPR compliance in relation to all storage and processing of personal data is covered by Deliverable 6.1 (DMP).

7.2 Data collection

Data resulting from questionnaires, interviews, focus groups, workshops and observations will be collected according to the minimisation principle. This means that only such data will be collected which is adequate, relevant, and limited to what is necessary in relation to the project aims. The informed consent statement (Annex A) will inform all research participants of the terms and conditions.

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[5] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

[6] Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

7.3 Anonymisation and Pseudonymisation

Any data will be anonymised, where possible, and else data will be pseudonymised. The Data Protection Working Party, an independent European advisory body on data protection and privacy, published a document on Anonymisation techniques (Opinion 05/2014 on Anonymisation Techniques, 2014). Here, generalisation and randomisation techniques are discussed. Also, pseudonymisation, which is different from anonymisation, is considered. For anonymisation, the data must be stripped until the data subject is no longer identifiable. Anonymisation techniques like aggregation will be applied if relevant. In this case, data is displayed only in total scores, omitting individual responses. (For example, age 25 will be grouped into the category age 20-30.) If anonymisation is not achievable, pseudonymisation techniques can be applied so that the source of information cannot be traced back to the data. Direct identifiers (e.g. names) will be replaced with indirect identifiers (e.g. numbers). Data masking could be applied, where some personal identifiers are stripped out while others remain.

7.4 Data Security, storage, and encryption

Practical data security, storage and encryption measures provided by the European University Institute (EUI, 2019) that will be used where possible:

- User authentication: verify a user by a password, considering length, a mix of letters and no ties to your personal information;
- Access control: a mechanism to allow or deny access to specific data;
- Storage security: storing data in a way that prevents unauthorised access, for example, by operating system controls, use of passwords to access electronic files, local encrypted storage, database encryption;
- Data retention will cover the duration of the project and no longer;
- Communication security: safe electronic communication for transferring data: encrypted communications (SSL/TLS, secure URLs starting with https://); firewall systems and access control lists; anti-virus and anti-malware systems; protect data when physically transferred.

7.5 Data Transfer

Regarding the data collected for the communication and dissemination activities of the project, they will not be transferred to third parties either in the original form or in copies. Data might be published in reports, scientific publications, and other forms of publication, however, in anonymised form only.

The project core group, including legal experts at various partner institutes, will guarantee that this process, including the information for the individuals about data protection issues, fully complies with national and EU laws.

7.6 Informed consent procedure

Individuals participating in any form of stakeholder engagement activities involving data collection will be informed comprehensively about the intended use of the information collected from them and have to agree to the data collection for scientific purposes with their active approval in the form of written consent. In addition, individuals will be informed about data security, anonymity and use of data as well as asked for in accordance.

Website data collection

The CROSSGOV website should serve as a source of information on the project. The following personal data might be stored while using the website: name of internet domain, IP address of the accessing computer, pages visited, and actions performed throughout the website.

The data may be processed to optimise the website by improving the quality of the available information, website ergonomics, website management, and website navigation and to generate statistics from this information. The collected data will not be provided to any third party or processed in a manner inconsistent with the purposes for which they have been initially collected, without prejudice to any applicable legal provision of any kind, particularly in the matter of data retention, as specified in D 6.1 (DMP).

The website is anticipated to store cookies. These are small text files that are saved on the computer, which the browser can access. They increase the user-friendliness of the website. In case the website uses cookies, a pop-up will ask you for permission first.

8. Implementing IPR in CROSSGOV

To ensure that all knowledge and intellectual property generated by CROSSGOV is managed correctly and adequately protected, the CROSSGOV Consortium Agreement addresses the ownership and management of both project results and pre-existing rights (i.e. background included), as well as access rights and confidential information. Results are owned by the partner that generates them, including the case of joint ownership and the principles governing this.

The main IPR issues to consider in CROSSGOV are copyright and database protection in relation to datasets and publications while following the EC's "Open Science, Open Innovation, Open to the World" agenda and applying the FAIR principles to all project outputs as well as to the primary data collected. As stated in DG Research & Innovation's study on Open Science (OS) and Intellectual Property Rights (2022)[7], the OS paradigm poses new challenges to IPR, but the two are in no way incompatible.

The CROSSGOV research results will be made openly available unless otherwise explicitly specified and under the conditions that no confidential information is involved, and that appropriate identification of origin and conditions of reuse is applied (e.g. CC licenses)[8]. HEU requires typically CC-BY, which means an explicit obligation to license the publication" under the latest available version of the Creative Commons Attribution International Public License (CC BY) or a license with equivalent rights. An exception exists for monographs and other long-text formats, where "the license may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND)". (see GA, Annex 5, Article 17).

[7] Available at: https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/open-science-and-intellectual-property-rights_en
[8] Available at: https://creativecommons.org/licenses/?lang=en

Findable The community can find the data and metadata after publication using a search tool.	**Accessible** (Meta)data are accessible and can therefore be downloaded by other researchers using their identifiers
Interoperable Both the data and the metadata should be described following the rules of the community, using open standards, to allow for their exchange and reuse	**Reusable** (Meta)other researchers can reuse data since their origin and conditions of reuse are clear

Table 1 Clarification of the FAIR principles[9]

D. 5.5 (PDEC) will further address the protection of IPR in relation to the concrete tools, methods, and means of dissemination of exploitation applied in the project (e.g. research publications).

D. 6.1 (DMP) will further address the protection of IPR in relation to the findability, accessibility, interoperability, and reusability of primary data produced under CROSSGOV.

[9] Available at: https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/open-science-and-intellectual-property-rights_en

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10. Annex A Document of Informed Consent

PROJECT TITLE	CROSSGOV
START DATE OF THE PROJECT	01-09-2022
END DATE OF THE PROJECT	31-08-2025
PROJECT WEBSITE	www.CROSSGOV.eu

You have been invited to participate in research under the CROSSGOV project through a questionnaire, interview, focus group, or workshop. Before participating, please read the information below carefully. If statements in the document are unclear, do not hesitate to ask the contact researcher for clarification.

1. Project summary

The three-year CROSSGOV project aims to enhance knowledge on how coherence and cross-compliance of marine-related policies and legislation affect the ability to realise the goals of the EU Green Deal for the protection of marine ecosystems and biodiversity and to co-create proposals and roadmaps towards this end. A core strength of CROSSGOV is the close collaboration with the policymaking and policy implementation community that will be engaged in co-creating knowledge and recommendations for solutions. The background for the project is the complex multi-level and multi-sector governance system created by global and regional international frameworks, the EU, and the European coastal states. This policy landscape has not managed to halt the degradation of European seas and will be challenged further by the EU Green Deal's call for transformative changes. Based on scenarios and methodological guidance for studies of coherence, cross-compliance and scientific advice, the project will analyse how policies and legislation at various levels support or impede progress towards the Green Deal in the maritime domain. The practical results of attempts to implement the different requirements will be studied in three regional cases (the North Sea, the Baltic, and the Mediterranean) and five national cases (Finland, Norway, the Netherlands, France, and Italy). The insights gained will be discussed with CROSSGOV's Stakeholder Forum to co-create recommendations for better-integrated policies towards implementing the Green Deal in the marine context. The innovative, web-based, and fit-for-purpose roadmaps and methodological guidelines will enable policymakers and policy implementers to effectively foster environmentally sustainable law and governance that is fit-for-purpose for delivering the societal transformation called for.

2. Purpose of data collection

You have been invited to participate in a questionnaire, interview, focus group, or workshop. Resulting data will be expressly used to: ……

3. Benefit of participation

Participation is entirely voluntary, and you may not benefit directly. However, you will make a substantial contribution to the CROSSGOV project aims.

4. Risks of participation

There are no risks anticipated for participation.

5. Compliance with ethical and legal regulations

CROSSGOV complies with EU and national ethical and legal regulations, including the EU's GDPR (General Data Protection Regulation 2016/680) framework.

6. Privacy and data protection

Data resulting from surveys and interviews will be recorded and stored on secure servers. This data will not include any personal identification, so that data cannot be traced back to you as the data source. Data might be processed and analysed for publication in reports, scientific journals, and other forms of project outputs only in anonymised form. None of the data will be transferred to third parties. The retention time of the original research data is the same as the project duration. However, the anonymised resultant data may be stored for extended periods to be used in future research.

7. Withdrawal of participation

At any point, you may withdraw from participation by stopping the questionnaire, interview, focus group or workshop. This includes to have data deleted.

8. Researcher Contact

In case of any issues or questions, you can contact:

Name: …… and contact: ……

9. Consent statement

By signing this form, I state that I have read all information on this document of informed consent, I understand the information provided, and I agree with the terms and conditions provided on the informed consent document.

……..	……..	……..
Research Participant	Signature	Date

……..	……..	……..
Researcher	Signature	Date