

BRIEF

BIOROBOTICS RESEARCH AND INNOVATION ENGINEERING FACILITIES

D.7.1. SETUP OF THE LAW AND POLICY HUB

LaPoH



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DISCLAIMER

This project has received funding by the Ministero dell'Università e della Ricerca (MUR), Direzione generale dell'internazionalizzazione e della comunicazione within the framework of the National Recovery and Resilience Plan (NRRP) within the call for proposals framework REFORMS AND INVESTMENTS UNDER THE RECOVERY AND RESILIENCE PLAN – Next Generation EU, Intervention field 6: Investment in digital capacities and deployment of advanced technologies DESI dimension 4: Integration of digital technologies + ad hoc data collections 055 - Other types of ICT infrastructure (including large-scale computer resources/equipment, data centres, sensors and other wireless equipment). Mission 4 – “Education and Research” Component 2: from research to business Investment 3.1: “Fund for the realisation of an integrated system of research and innovation infrastructures Action 3.1.1 “Creation of new research infrastructures strengthening of existing ones and their networking for Scientific Excellence under Horizon Europe.

GLOSSARY

1. D: Deliverable
2. LaPoH: Law and Policy Hub
3. NNRP: National recovery and resilience plan
4. M: Milestone
5. WP: Work Package

1. SETUP OF THE LAW AND POLICY HUB

This document is the first deliverable of the Work Package 7 (WP7) “Legality-attentive BioRobotics Science and Policy-making” of the BRIEF project, which is carried out by the LIDER-Lab of Sant’Anna Advanced School of Studies. WP7 has three main objectives: 1) performing cross field regulatory analyses; 2) designing and advising on relevant policies; 3) developing legal-ethical awareness in biorobotics research.

This first deliverable D.7.1. contributes to the achievement of the second objective and is based on the creation of a Law and Policy Hub (LaPoH) which will be able to advise and to be consulted in-house by all the participants of the project regarding the challenges emerging from the application of the current and prospective legal framework to research and innovation in BioRobotics, both at an EU and at an Italian level. Various fields of law are concerned and range from data protection and intellectual property to health law. They will be detailed below. LaPoH will also give advice on ethical issues that arise from the design and use of BioRobotics devices. LaPoH’s activity is geared toward a more sustainable, safe and compliant development and adoption of Biorobotic devices.

1.1 The Structure of the document

This deliverable describes part of the activities and outcomes of WP7 first outputs at month 4, in three sections. The content of this deliverable will be further complemented by D.7.2. which describes the stakeholders’ strategy and engagement. This section describes the structure of the document (Section 1.1), followed by the description of the Law and Policy Hub (LaPoH), its relevance to the BRIEF project (Section 1.2.). The following section offers a detailed overview of the activities that are carried out to establish LaPoH. The section contains a brief paragraph about the stakeholder engagement which will be described in detail in D.7.2 reporting on the engagement strategy of LaPoH (Section 2.1.). Section 2.2. contains an explanation of the scope and functions of LaPoH, while Section 2.3 offers a synthesis of the organisational structure of the LaPoH’s Advisory Board that will advise LaPoH’s activities (1.3.). In Section 3, a synthesis of the outcomes of this first part of the project and conclusive remarks will conclude the document. The Annexes include the regulation of the LaPoH’s Advisory Board in English (Annex III) and Italian (Annex II), as well as its composition (Annex III and IV).

1.2 The Relevance of LaPoH for the BRIEF project

Establishing the LaPoH is necessary for the completion and effectiveness of the activities within the BRIEF project for several reasons. First, from a regulatory and ethical point of view, BioRobotics research and innovation is at the crossroad of a number of existing, emerging and prospective sets of legal rules. Second, its development and deployment are extensively dependant on data, AI, health-related research and their respective regulatory frameworks. Third, it will increasingly depend on the data infrastructures that are set up at a national and European level, on the progress that they will be able to convey (e.g., genomic data as a test bed for the construction of the European Health Data Space), and on the complex regulatory framework of the technologies they incorporate (e.g. AI, personal and non-personal data, public sector information (PSI), intellectual property and trade secrets, platform liability

and regulation, data sharing and service providers, clinical trials, medical device regulation, product safety and liability etc).

In order to ensure that the legal research and the outputs of WP7 are shared efficiently among the BRIEF project participants, it is essential to create a strategy that involves both external stakeholders (D.7.2) and BRIEF project participants. As a preliminary step, it is necessary to create a specific organisation that is specialised in the analysis and interpretation of the relevant legal provisions and policy documents that are applicable to the BRIEF project. This organisation is the Law and Polic Hub (LaPoH), will physically be based at the SSSA and linked to the LIDER-Lab.

2. ACTIVITIES

2.1 Stakeholders' involvement

Throughout the first months, the LIDER-Lab team actively worked in collaboration with the other BRIEF project partners to find the most relevant regulations and policies that need to be analysed for the project¹ and to create a strategy that will involve external stakeholders (see D.7.2). The connection and relationship with external experts will provide LaPoH with a more solid and visible position in Italy and the EU, as its activities and missions will be known by the relevant private and public institutions working in the same field or related ones.

2.2 The LaPoH's set-up

LaPoH's composition is the result of the collaboration of the LIDER Lab and the other BRIEF project partners. In particular, LaPoH is composed of Professors Denise Amram, Giovanni Comandè, Maria Gagliardi, Caterina Sganga and the researchers affiliated to SSSA (technologists, PhD students and post-doctoral researchers) with fields of interest connected to the projects. In order to coordinate the activities of the hub, a public competition was published on 23 December 2022 with the aim of hiring two technologists specialised in privacy and data protection. The hired technologist will start their two-years contract in March 2023².

The LaPoH will consist in a pool of experts that will help the other BRIEF project partners to strengthen, consolidate and enlarge a distributed infrastructure on BioRobotics for Innovation Engineering as a reference for worldwide researchers operating in the field. The infrastructure will continue its activities even after the end of the BRIEF project. In particular, the role of LaPoH is to carry out high-level legal and policy analyses concerning enacted or proposed EU regulations that have an impact on BRIEF's research and innovation activities. Examples of the relevant regulations and fields of law are:

- o Tort law, insurance, and personal injury damages
- o Property law, intellectual property, and trade secrets

¹ As an outcome of this collaboration a cross-sectoral analysis will be written in some of the WP deliverables (in particular, see future D.7.3, 4, 5).

² All the relevant documents concerning the hiring process could be found at the following link <https://www.santannapisa.it/it/selezioni/pnrr-selezione-pubblica-tecnologo-brief-categoria-ep1-privacy>.

- o Obligations, contractual relationships, and liabilities
- o Personal identity, robots or AIs as legal entities or agents
- o Personal relationships in the workplace, medical-patient and care-relationships, family environment
- o Digitalization of private and public services (digital platforms, public services information)
- o Law and economics implications in the insurance market-
- o The regulation of human-robot interactions in the workplace, healthcare sector, family relationships, public sectors, and industries (including creative ones).
- o The ethical-legal implications for a sustainable and efficient research (initiatives under CTR, MDR, AI, GDPR, NON-PERSONAL DATA FLOWS)

The expected results will also include the analysis of the regulatory needs for the creation of legally compliant and sustainable BioRobotics products and devices. Moreover, this WP, and this deliverable in particular, also considers that LaPoH's function will help the project reach some of the Sustainable Development Goals (SDG), and, more specifically, SDG4 Quality Education, SDG9 Industry, innovation and infrastructure, SDG10 Reduced inequalities, SDG11 Sustainable cities and communities, SDG12 Responsible consumption and production, SDG16 Peace, Justice and strong institutions.

In order to select LaPoH's members, the following selecting criteria were employed: LaPoH had to be composed by a scholars specialised in the legal and ethical topics that are relevant for BRIEF, such as data protection or intellectual property, and by field-related experts and stakeholders. In order to maximise the efficiency of LaPoH, at least in this initial phase, there was the need to keep a simple and flexible structure, which could rely on pre-existing, close-knit working research groups, such as the Permanent Observatory on Personal Injury Damages group at SSSA. This two-fold objective was ultimately achieved by leveraging existing scientific collaborations within the LIDER-Lab (SSSA) and those with other partners. Such collaborations are the foundations of the Advisory Board, which will be described in the next sub-paragraph, composed by external scholars, domain experts and other stakeholders.

2.3 The LaPoH's Advisory Board set-up

A pool of experts within the LaPoH was created to strengthen LaPoH's knowledge and expertise by promoting meeting opportunities, events, and networking, as well as by supporting communication campaigns with the aim of raising awareness about LaPoH's mission. The experts selection for the Advisory Board was primarily organised by the LIDER-Lab in accordance with a survey of the partners of the BRIEF project.

The Advisory Board is composed of high-profile ethical, social, and professional representatives coming from academia, business, professional associations, and the third sector, such as associations, and both from public and private institutions and organisations. The members can range from 6 to 10, one being the President that can nominate a Vicepresident. All the rules concerning the functioning of the Advisory Board are described in Annex I (in English) and Annex II (in Italian). One of the goals of the Advisory Board is to make LaPoH's mission and structure last beyond the formal duration of the BRIEF project.

3. OUTCOMES AND CONCLUSIONS

In conclusion, the first part of the WP has been concluded successfully as LaPoH was set-up as well as its Advisory Board. All the decisions that were taken intended to secure that prestigious experts were able to allow BRIEF partners to develop BioRobotics devices that could be ethically and legally compliant with relevant EU and Italian regulations and policies that could influence the development of BioRobotic devices. Moreover, in setting up LaPoH and its Advisory Board, the BRIEF partners wanted to create a structure that will last even after the BRIEF project ends.

ANNEX I. REGULATION OF THE LAPoH'S ADVISORY BOARD (EN)

Art. 1 - Institution

1. The *Law and Policy Hub* (LaPoH, the organisation) Advisory Board is a Committee composed of high-profile ethical, legal, social, and professional representatives coming from academia, business, professional associations, and third sector, such as associations, and from public and private institutions and organisations.

Art. 2 – Functions and competences

1. The LaPoH's Advisory Board performs the following functions:

- a) strengthening LaPoH's knowledge and expertise by promoting meeting opportunities, events, and networking, as well as supporting communication campaigns with the aim of raising awareness about LaPoH's mission;
- b) supporting the growth of LaPoH 's internal capacities with its own professional skills, also through the participation in LaPoH's activities.

Article 3 - Composition and terms of appointment

1. The members of the Advisory Board are appointed by the Work Package leader after consultation with the Project Co-ordinator. The appointment is ratified by the Project Assembly. The number of members can range from a minimum of 6 and a maximum of 10.

2. The members of the Advisory Board are appointed to ensure the presence of the following figures, which can also be secured thanks to the interdisciplinary expertise of the individual members:

- 1. a data protection expert;
- 2. an expert in regulation of technologies and markets;
- 3. an expert in clinical studies;
- 4. a representative of the industrial sectors that are relevant for the BRIEF project's field of application;
- 5. an exponent of the demands of the recipients of related products and services (e.g., medical personnel);
- 6. an exponent of the demands of the final users and recipients of services (e.g., patients' association);
- 7. and at least one member of LaPoH.

3. The Advisory Board members serve for a three years' term and may be reappointed for a further term.

4. The Advisory Board members terminate their service due to resignation.

5. The Advisory Board composition shall be made public.

6. The position of Member of the Advisory Board shall not give rise to any indemnity or compensation of any kind, the said position being strictly voluntary. This is without prejudice to the right of the LaPoH to only provide for the payment of expenses related to the mere reimbursement of living costs that may be incurred in the performance of the offices and in any case within the limits established by the internal regulations of the SSSA.

Article 4- LaPoH's President and Vice-President

1. The President of the Advisory Board represents the Advisory Board and LaPoH as an organization in official contexts. The President is responsible for the planning of the activities of the Advisory Board according to the competences set out in Article 2.
2. The President is the chair of the Advisory Board meetings and serves the term for three years. They are elected among the members of the Advisory Board, in the first plenary meetings with a majority of votes. They can be re-elected once. They schedule and set the agenda for the Advisory Board meetings. They can cast the deciding vote in disputed cases.
3. The President may appoint a Vice-President among the Advisory Board members. The Vice-President serves a three-year term and is renewable for one more term. The main function of the Vice-President is to support the President with the internal organization of the Advisory Board's activities, including taking minutes of meetings. They can fill in and exercise the functions of the President whenever the President is gravely incapacitated and has expressly authorised them in writing. If the Vice-President is not appointed all the previous tasks are carried out by the President.

Article 5 - Functioning

1. The meetings of the Advisory Board are convened and chaired by the President of LaPoH or the Vice-President.
2. The Advisory Board shall normally meet twice a year at the seat office of LaPoH. Meetings shall be convened at least fifteen days before the date of the meeting or, on an urgent basis, at least eight days in advance by electronic means. Meetings can be held also with distant means of communications.
3. For meetings to be valid, half plus one of the Advisory Board members must be present, not counting those excused in writing. Resolutions are passed by the majority of those present.
4. The President of LaPoH or the Vice-President shall prepare the agenda to be discussed by the Advisory Board.
5. Meetings of the Advisory Board may also be held remotely provided that each of the participants can be identified and can follow the discussion and intervene in real time.
6. Other persons may attend the meetings of the Advisory Board in an advisory capacity at the invitation of the President of LaPoH or their delegate.
7. Minutes of the meetings shall be taken and transmitted within one week to the members and the President of LaPoH.

Article 6 - Tasks

1. The Advisory Board has the task of identifying an effective link between the BRIEF project's objectives and the needs of public and private organisations.
2. The Advisory Board
 - a) has a support function for the definition of the strategic programming plan of the LaPoH activities, consistent with the objectives of the BRIEF project;
 - b) suggests new actions or development ideas for the continuation of the infrastructure;
 - c) identifies and signals opportunities for raising resources, partnerships and sponsorships;

d) facilitates relations between the LaPoH and economic, institutional and social realities with regard to aspects concerning relations, communication and the development of agreements with businesses and public and private administrations.

3. The President of LaPoH may confer specific assignments, of a temporary nature, to individual members of the Advisory Board, defining their contents and operating methods, without prejudice to their free and consultative nature.

ANNEX II. REGOLAMENTO DELL'ADVISORY BOARD DEL LAPOH (IT)

Regolamento Advisory Board del Law and Policy Hub

Art. 1 - Istituzione

1. L'Advisory Board del Law and Policy Hub (LaPoH, organizzazione) è un organismo indipendente formato da esponenti di elevato profilo etico, sociale e professionale provenienti dal mondo accademico, dal mondo delle imprese, delle professioni e del terzo settore, come le associazioni, delle istituzioni e delle organizzazioni sia pubbliche sia private.

Art. 2 - Funzioni

1. L'Advisory Board del LaPoH svolge le seguenti funzioni:

- a) rafforzamento delle conoscenze dei membri del LaPoH, promuovendo occasioni di incontro, eventi e networking, con finalità di sensibilizzazione, sostenendo l'adesione di singoli e realtà associate alle campagne di comunicazione;
- b) crescita delle capacità interne dell'organizzazione con le proprie competenze professionali, anche attraverso la partecipazione ad attività dell'Ente.

Art. 3 - Composizione e durata in carica

1. I componenti dell'Advisory Board sono nominati, in numero di minimo 6 e massimo 10, dal WP leader sentita la Coordinatrice di Progetto. La nomina è ratificata dall'Assemblea del progetto.

2. I componenti dell'Advisory Board sono nominati in modo da assicurare la presenza delle seguenti figure che può essere garantita anche grazie alla competenza interdisciplinare dei singoli membri;

- 1. un/a esperto in tema di protezione dei dati
- 2. un/a esperto in tema di regolazione delle tecnologie e dei mercati
- 3. un/a esperto/a in studi clinici
- 4. un/a esponente dei settori industriali coperti dal progetto BRIEF
- 5. un/a esponente che rappresenti le istanze dei destinatari dei prodotti e servizi correlati (e.g. personale medico)
- 6. un esponente che rappresenti le istanze degli utenti finali (e.g. associazioni di pazienti)
- 7. almeno un membro di LaPoH

3. I componenti dell'Advisory Board rimangono in carica tre anni e possono essere riconfermati per un ulteriore mandato.
4. I componenti dell'Advisory Board decadono dalla carica per dimissioni.
5. La composizione I nominativi, la qualifica ed il curriculum vitae dei componenti dell'Advisory Board è resa pubblica sono resi pubblici.
6. La qualifica di componente dell'Advisory Board non dà luogo a indennità o compensi di sorta, essendo il predetto incarico a titolo rigorosamente volontario. È fatta salva la facoltà da parte del LaPoH di prevedere esclusivamente la corresponsione di rimborsi spesa relativi al mero ristoro dei costi vivi eventualmente sostenuti nell'ambito dello svolgimento degli incarichi stessi e comunque nei limiti stabiliti dalla normativa interna alla SSSA.

Articolo 4 - Presidente e Vicepresidente del LaPoH

1. Il Presidente/la Presidente dell'Advisory Board rappresenta l'Advisory Board e LaPoH come organizzazione in contesti ufficiali. Il/la Presidente è responsabile della pianificazione delle attività dell'Advisory Board secondo le competenze di cui all'articolo 2.
2. Il Presidente/ la Presidente presiede le riunioni dell'Advisory Board e resta in carica per tre anni. È eletto/a tra i membri dell'Advisory Board, nelle prime riunioni plenarie, con la maggioranza dei voti. Può essere rieletto/a una volta. Il/la Presidente programma e stabilisce l'ordine del giorno delle riunioni dell'Advisory Board. Può esprimere il voto decisivo nei casi controversi.
3. Il/La Presidente può nominare un/una Vicepresidente tra i membri dell'Advisory Board. Il/la Vicepresidente ha un mandato di tre anni ed è rinnovabile per un altro mandato. La funzione principale del/la Vicepresidente è quella di supportare il/la Presidente nell'organizzazione interna delle attività del Comitato consultivo, compresa la verbalizzazione delle riunioni. Può sostituire ed esercitare le funzioni del/la Presidente in caso di grave impedimento di quest'ultimo/a, che lo ha espressamente autorizzato per iscritto. Se il/la Vicepresidente non viene nominato, tutti i compiti precedenti sono svolti dal/la Presidente.

Art. 5 – Funzionamento

1. Le riunioni dell'Advisory Board sono convocate e presiedute dal/la Presidente del LaPoH o dal/la Vicepresidente se espressamente delegato/a.
2. L' Advisory Board si riunisce di norma due volte l'anno per svolgere le proprie attività presso la sede legale del LaPoH o in modalità remota. Le riunioni sono convocate almeno quindici giorni prima della data della riunione oppure in via urgente, almeno otto giorni prima in via telematica.
3. Per la validità delle riunioni è necessaria la presenza della metà più uno dei suoi membri non contando i giustificati per iscritto, e le deliberazioni sono assunte a maggioranza dei presenti.
4. Il/la Presidente del LaPoH o il/la Vicepresidente predispone l'ordine del giorno che sarà discusso dall' Advisory Board.
5. Le sedute dell'Advisory Board possono inoltre svolgersi in modalità a distanza a condizione che ciascuno dei partecipanti possa essere identificato e possa seguire la discussione e intervenire in tempo reale.
6. Alle riunioni dell'Advisory Board possono **partecipare**, in veste consultiva, altre persone, su invito del/la Presidente del LaPoH o il/la Vicepresidente.

7. Le riunioni vengono verbalizzate e trasmesse entro una settimana ai componenti, nonché al/la Presidente del LaPoH.

Art. 6 – Compiti

1. L’Advisory Board ha il compito di individuare un efficace raccordo tra gli obiettivi del progetto BRIEF e le esigenze professionali delle imprese e delle organizzazioni pubbliche e private relativamente ai fabbisogni espressi dagli stakeholder di riferimento.

2. L’Advisory Board:

a) ha una funzione di supporto per la definizione del piano strategico di programmazione delle attività del LaPoH , in coerenza con gli obiettivi previsti dal progetto BRIEF;

b) suggerisce nuove azioni o propone idee di sviluppo per la prosecuzione della infrastruttura;

3) individua e segnala opportunità di reperimento di risorse, partnership e sponsorship;

d) facilita le relazioni tra il LaPoH e le realtà economiche, istituzionali e sociali per quanto concerne gli aspetti riguardanti la relazione, la comunicazione e lo sviluppo di accordi con le imprese e le amministrazioni pubbliche e private;

3. Il/La Presidente del LaPoH può conferire a singoli componenti dell’Advisory Board specifici incarichi, di natura temporanea, definendone contenuti e modalità operative, fermo restando il carattere gratuito e consultivo degli stessi.

ANNEX III: ADVISORY BOARD COMPOSITION (EN)

1. Data protection expert: Professor **Gianclaudio Malgieri**, PhD, University of Leiden
2. Expert in regulation of technologies and markets: **Andrea Parziale**, PhD, University of Maastricht
3. Expert in clinical studies: Professor, **Annalisa Calabrò**, MD, PhD, Università Cattolica del Sacro Cuore, Roma
4. Representative of the industrial sectors which are relevant for the BRIEF project field of application: **Simona Crea**, PhD, IUVO
5. Exponent representing the demands of the recipients of related products and services: **Irene Giovanna Aprile**, MD, Fondazione Don Gnocchi, Roma
6. Exponent representing the demands of the final users and recipient of services (e.g., patients associations): **Sabrina Grigolo**, MD, EUPATi
7. LaPoH member: Professor **Giovanni Comandé**, PhD, LLM, Full Professor of Comparative Private law, Sant’Anna School of Advanced Studies
8. LaPoH member: **Arianna Rossi**, PhD, Sant’Anna School of Advanced Studies

ANNEX IV: ADVISORY BOARD COMPOSITION (IT)

1. Esperto in tema di protezione dei dati: Professor **Gianclaudio Malgieri**, Università di Leiden
2. Esperto in tema di regolazione delle tecnologie e dei mercati: Dottor **Andrea Parziale**, Università di Maastricht
3. Esperta in studi clinici: Professoressa e Dottoressa **Annalisa Calabrò** Università Cattolica del Sacro Cuore, Roma
4. Esponente dei settori industriali coperti dal progetto BRIEF: Dottoressa **Simona Crea**, IUVO
5. Esponente che rappresenti le istanze dei destinatari dei prodotti e servizi correlati (e.g. personale medico): Dottoressa **Irene Giovanna Aprile**, Fondazione Don Gnocchi, Roma

6. Esponente che rappresenti le istanze degli utenti finali (e.g. associazioni di pazienti): **Sabrina Grigolo**, EUPATi
7. Membro di LaPoH: Professor **Giovanni Comandè**, Professore Ordinario di Diritto Privato Comparato, Scuola Superiore Sant'Anna
8. Membro di LaPoH: Dottoressa **Arianna Rossi**, Scuola Superiore Sant'Anna

