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WP 2.4.4.1 “ACCLAIM”
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D5.1 Ethics	
Document number	LPA-WP2.4.4.1-EURECA/D-5.1.
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Keywords	Ethics
Abstract	The objective of this deliverable is to define the ethics requirements that the EURECA project must comply with. These will be based on the Ethics Self-Assessment, that was submitted with the initial proposal

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Version n°	**Issue Date**	**Reason for change**
A01	03/07/2019	First Draft
A02	24/07/2019	IFAM Review
A03	25/07/2019	Final Document

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

Partners involved in the document

No	Member name	Short name	Check (X) if involved
1	Airbus SAS	A-CE	
2	Airbus Operations SAS	A-F	
3	Airbus Operations GmbH	A-D	
4	Airbus Operations Ltd	A-U	
5	Airbus Operations SL	A-E	
6	Fraunhofer IFAM	IFAM	X
7	SFS intec GmbH	SFS	
8	Solvay Specialty Polymers	SOL	
9	Consiglio Nazionale Delle Ricerche	CNDR	X
10	IT+ Robotics SRL	ITR	X
11	Protom Group SPA	PG	X
12	Asociacion Centro Tecnologico CEIT-IK4	CEIT	
13	CT Ingenieros Aeronauticos, DE Automocion E Industriales SL	CTI	

Check X for every company involved
Check X with * for the main author/leader

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

TABLE OF CONTENTS

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

ACRONYMS LIST
(Acronyms not used in the document should be deleted from the table. Additional acronyms to be added to the table)

Acronym	Definition
A/C	Aircraft
AAR	Annual Activity Report
AB	Annual Budget
ACARE	Advisory Council for Aeronautics Research in Europe
A-CE	Airbus SAS
A-D	Airbus Operations Gmbh
A-E	Airbus Operations SL
AEA	All Electric Aircraft
A-F	Airbus Operations SAS
AFP	Advanced Fibber Placement
AGI-F	Aibus Group SAS
AIP	Annual Implementation Plan
ARM	Annual Review Meeting
CA	Consortium Agreement
CDR	Critical Design Review
CfP	Call for Proposals
CP	Core Partner
CROR	Counter Rotating Open Rotor
CSDP	Clean Sky Development Plan
CSMM	Clean Sky Management Manual
DoW	Description of Work
EC	European Commission
GA	Grant Agreement
GAM	Grant Agreement for Members
GAP	Grant Agreement for Partners
GB	Governing Board
IA	Implementation Agreement
IADP	Innovative Aircraft Demonstrator Platform
ITD	Integrative Technology Demonstrator
JTI	Joint Technology Initiative
JTP	Joint Technical Programme
JU	Clean Sky Joint Undertaking/ Clean Sky 2 Joint Undertaking
KOM	Kick-off Meeting
MC	Management Committee
n/a	Not applicable
PDR	Preliminary Design Review
PMC	Project Management Committee
PO	Project Officer
PoC	Point of Contact
QR	Quarterly Report
RfC	Request for Change
SC	Steering Committee
SoW	Statement of Work
SPD	System & Platform Demonstrator
STAB	Scientific Technical Advisory Board

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

1 INTRODUCTION

The objective of this deliverable is to define the ethics requirements that the EURECA project must comply with. These will be based on the Ethics Self-Assessment, that was submitted with the initial proposal, which covered topics such as human and animal rights, treatment of personal data and the potential of developing technology for military applications. By ensuring compliance with ethics guidelines and evaluating all direct and indirect consequences of the work carried out in the project, it can be ensured that all proceedings will have minimal impact on:

- National & Global security
- Non-proliferation & terrorism
- International legal obligations
- Human rights & internal repression
- Animal welfare

This deliverable will assume a more practical approach to ethics compared to the Ethics Self-Assessment which had the goal of identifying which ethical domains required consideration during project work, see Appendix A: Ethics Self-Assessment.
Overall there were only few concerns, which were all focused around the collection of data and working with human subjects.
Although this proposal is about investigating and delivery new prototypes for the cooperative assembly of the aircraft, which are not expected to involve human experimental subjects except the trained operator of the EURECA consortium likey the memer of ACCLAIM consortium. Requirements for these two areas, and actions to ensure compliance will be addressed in this deliverable.

2 PROTOTYPE SECURITY

2.1 CONTEXT

When being used as an assistive device, robotic exoskeletons are designed to interact continuously with its user, are in continuous contact with the user, and occupy the same space and time. The close proximity between users and exoskeletons exposes the users to multiples of hazards that require extreme consideration. While standards are published to guide the inherently safe design of service, industrial and personal care robots [12] (ISO: 13482, ISO: 10218/1 and ISO: 10218/2), there are no standards currently published that manage industrial worker exoskeletons. Additionally, the harmonised standards published under the Machinery Directive do not relate to a machine and wearable tool combined device.

The empowering device EURECA is going to develop will be directly controlled by the users' body movements, and sensor feedback systems. Based on users' requirements, the device will be designed to accomplish specific tasks within specific environments, and comprised of a set of components in a specific configuration.

However, differently from the concepts stated within the DoA, in agreement with the TM, and according to the ERS of the submitted proposal, the exoskeleton structure has been partially modified in order to:

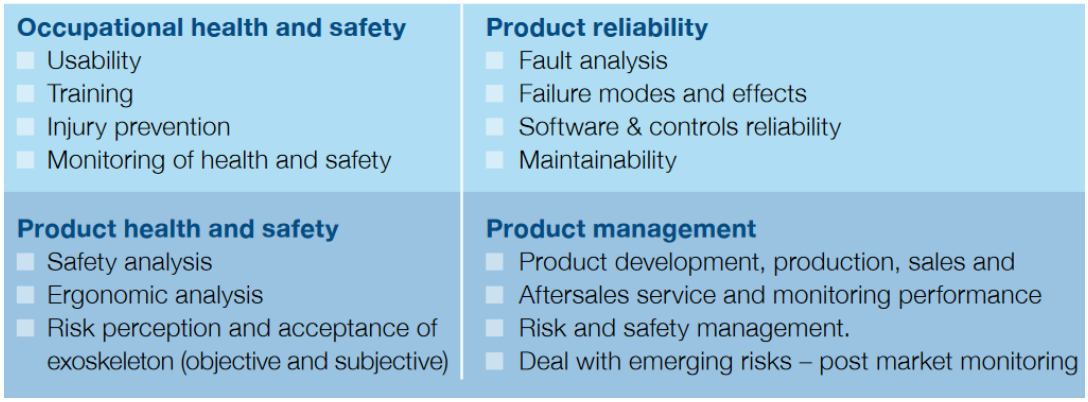
- Avoid any wearibility,
- ease the operator usage and
- reduce dramatically safety issues, and improve the acceptance from the user as a standard machine, simplyfing the ethics assessment

The reference standard for the safety issues in using the robot in collaboration with the humans are in the table below.

Published Standard	Consideration for selecting to further develop
ISO 13482 – 2014: Robots and robotic devices - Safety requirements for personal care robots	Specifies requirements & guidelines for the safe design, protective measures, and information for personal care robots. This is the only published standard in which the term exoskeleton is provided to refer to a physical assistant robot
ISO 10218 /1-2011: Robots and robotic devices - Safety requirements for Industrial Robots, Part 1 Robots	Specifies the requirements and guidelines for the inherent safe design, protective measures, and information for use of industrial robots
ISO 10218/2-2011: Robots And Robotic Devices- Safety Requirements for Industrial Robots: Part 2 Robot Systems & Integration	Specifies requirements for the integration of industrial robots and industrial robot system as defined in ISO 10218 - 1

Therefore, the safety of the exoskeleton results from a multi-level set of actions, and methodologies adopted in all the phase of the exoskeleton conception, design, realization and test (see Figure below).

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019



In the safety and risk management process of the project, risk assessment procedures are applied by Human Factors engineers, ergonomists, and designers. The process will be coordinated by safety and health management experts throughout the projects lifecycle.

2.2 TECHNICAL ACTIONS

The Task 2.7 has been the core of the design of the HW and SW solutions provided in the EURECA project, and the design choices have be evaluated in term of the risk associated.

The risk assessment of each component, has been a continuous action during the project. Potential hazards have been identified and documented in the technical deliverables.
Specifically, the safety-related actions (T2.7) have been:

1. Specific design requirements for the empowering device hardware & software components and systems
    - Actuating controls: the driver have been selected to allow a dual-control running. The first resident on the firmware of the actuator driver, and the second one remoted thorugh EtherCat Fieldbus. Misalignement due to incorrect measure are catched and considered an emrency situation
    - Emergency start-up & stop controls: have been deployed according to the standards
    - Imitators - speed control, range of movement, support systems have been deployed according to the standards
    - Safety Stop has been integrated within the system
    - Protective measures and safety device requirements in the event of emergency, error, or failure e.g. emergency release, emergency stop

Remarkably, the technologies that EURECA is going to deliver during the project have to be considered prototype (TRL4/5), and not certifiable systems.

This implicates that:

- The project will demonstrate the technical feasibility of the concept, and it will demonstrate that an industrial certifiable solution can be achieved
- The project will identify the roadmap that could allow the final development of the devices developed in EURECA

2.3 PROPOSAL CONTEXT

Please indicate if your proposed project involves:

- activities or results raising security issues: (NO)
- 'EU-classified information' as background or results: (NO)
- potential for military applications: (NO)
- any material imported from non-EU countries into the EU: (NO)
- any material exported from the EU to non-EU countries: (NO)

3 ETHICS ASSESSMENT

In the section, the most common ethic issue related to the adoption of robotics in application scenario involving humans are reported.

For each ethic issue a proper section is listed below, where the mitigation action is described.

3.1 PROCEDURES FOR MONITORING THE ETHICAL ISSUES THROUGHOUT THE PROJECT

Work done by EURECA partners and its beneficiaries will conform to relevant EU legislations, such as:

- The Charter of Fundamental Rights of the EU (specially Art.3: right to the integrity of the person; and Art. 8: protection of personal data)
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Treaty on the European Union (TEU): Article 6
- The "framework" Directive on occupational safety and health: Council Directive 1989/391

This will be ensured through continuous monitoring of project activities across all Work Packages. If any ethical concerns are identified by members of the consortium, these can be escalated to the project coordinator or the steering committee, depending on the nature of the concern.
Practically, this is done through our collaborative platform MS sharepoint, where we have created a separate channel for all ethics-related communication and file sharing. In this channel, there is an Ethics Issue Tracking functionality where all project participants are able to create new entries. The Ethics Officer subscribes to this channel and will always be informed if new entries have been made. Depending on the evaluation by the submitter and the Ethics Officer, the issue can be marked for escalation to the Steering Commetee.
See Appendix D for an overview of the details tracked for ethical issues (source from website version at July 2019).

3.2 CRITERIA THAT WILL BE USED TO IDENTIFY/RECRUIT RESEARCH PARTICIPANTS

We do not expect that any of the realistic trials in EURECA will require recruited research participants by the end of the project. If tests involving human subjects are required to validate or expand on safety protocols, it will be robot developers acting as test subjects.

3.3 COMPANY EMPLOYEES TAKING PART AS PARTICIPANTS IN THE TESTING

The main concern is about the definition of measures to ensure that, in the case of company employees taking part as participants in testing, their consent is fully voluntary and informed, and not unduly influenced by concerns for their future employment.

The mitigation action consists of we do not anticipate that the nature of the realistic trials will lead to tests that in any way can be harmful or cause discomfort to humans. However, in such case, we would ask for informed consent procedure to be reported.

3.4 TEMPLATES OF THE INFORMED CONSENT FORMS AND INFORMATION SHEET

Within the EURECA project there could arise the need to have an informed consent form, even though we do not expect to use research participants for testing. Please see a draft of this form in Appendix B. The draft primarily focus on what topics/areas need to be addressed in the form on a general level.

3.5 CHILDREN AND/OR UNABLE ADULTS' INVOLVEMENT

The ethics concern is about the possibility the applicant must clarify how consent/assent will be ensured in case children and/or adults unable to give informed consent are involved

This concern is out of scope for EURECA, since the only trained workers will be involved in the project.

3.6 VULNERABLE INDIVIDUALS'/GROUPS INVOLVEMENT

The ethics concern is about the possibility the applicant must clarify whether vulnerable individuals/groups will be involved. In such a case, details must be provided about the measures taken to prevent the risk of enhancing vulnerability/ stigmatization of individuals/groups.

This concern is out of scope for EURECA, since only trained workers will be involved in the project.

3.7 DATA PROTECTION DIRECTIVE MANGEMENT

The ethics concern is about the availability of copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority that must be submitted (which ever applies according to the Data Protection Directive (EC Directive 95/46, Regulation (EU) 2016/679 and Directive (EU) 2016/680 as well as the national law).

These requirements will be included in the agreements between EURECA and workers' factories as needed. The data management, together with the method applied to fulfill with EU General Data Protection Regulation (GDPR). The appointed Data Protection Manager from CNR will have the responsibility to handle the process according to the existing laws.

3.8 SENSITIVE DATA COLLECTION

The ethics concern is about the justification that must be given in case of collection and/or processing of personal sensitive data.

The EURECA project will comply with EU law on the General Data Protection Regulation (GDPR):

- Only Data strictly required for the purpose is collected and used
- In the case of sensitive data as referred to as "special categories of personal data" data collection will be subjected to informed consent.

The only personal data that we expect to collect in the project is names and contact information of people that are participating in the experiments. These will not be published, and only stored during the time that it has relevance for the ongoing work, which at the latest will mean deleting this information once the project

has ended. Should it become relevant to collect additional personal sensitive data, then continuous justification will be mandatory. This could for instance be opinions about working in cooperation with robots, feelings regarding safety around a robot, opinions about wearing an exoskeleton, acceptance of working in an environment in harmony with robots and etc.

3.9 SENSITIVE DATA LIFECYCLE

The ethics concern is about the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation (including the new data protection laws coming into force in May 2018 (Regulation (EU) 2016/679 and Directive (EU) 2016/680).

In the case the data will be acquired, the EURECA project will provide a detailed report on the data Management Plan.

3.10 TEMPLATES OF THE INFORMED CONSENT FORMS AND INFORMATION SHEET (FOR THE DATA COLLECTION).

We will not have EURECA fill informed consent forms for storing their contact information, as this is not considered personal sensitive. We do not expect to collect personally sensitive data in any of the EURECA experiment. Should this change, then it would be quite straight forward to adapt the template from Appendix B to cover personal data. We would have to address two additional areas, which are how long the data would be stored, and the safety of the storage platform.

3.11 DETAILS ON MEASURES TO PREVENT MISUSE OF RESEARCH FINDINGS

Details on measures to prevent misuse of research findings should be provided togheter a risk-assessment including details on applicable legal requirements and the measures they take to prevent misuse must be prepared.
However, we find this to be inapplicable in the case of the EURECA project, as the nature of the research conducted in the project makes misuse very unlikely. Although in case of any doubt after selecting a project or during the project, the Ethics officer.

3.12 COMPLIANCE WITH THE ETHICAL STANDARDS OF H2020

Each H2020 project provides an in-depth analysis of the ethical issues raised by the actions investigated in the project and the measures that will be taken to ensure compliance with the H2020 ethical standards, including responsible research.

Collaborative robotics will have an impact on employment in various sectors, as well as the aerospace sector. Therefore, the EURECA consortium took part in the debate on socio-economic impacts with activities to disseminate the general public and communication activities with interested parties such as labor and industry organizations, and will continue on these actions until the end of the project same.

Particular attention was paid to the safety of collaborative robotics.
From an ethical point of view, an important issue within the EURECA project is the balance between practicality and security. For the devices we have tried to develop contents that can be used by end users, robot developers and system integrators, in a safe and intuitive manner.
To achieve this goal, we have tried to guarantee the use of the best practice and technology at the industrial level.

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

4 CONCLUSION

Within the EURECA project we have four domains of ethical challenges, where we have to ensure compliance with ethical requirements, all of which are addressed in different ways:

- Compliance for EURECA project/consortium activities

  We do not expect the proceedings of the EURECA consortium partners to raise many ethical concerns, as we will not be using research participants for development of new usage procedure. Generally, the work can be categorized as safe and responsible research.

- Compliance for the general EURECA project outcome/results

  The socio-economic consequences of the EURECA project have been identified and are considered part of the technological trend in Europe, where an increasing number of collaborative robots are entering the market. The EURECA project will promote this development, which in the project is not considered as a negative. However, as with all technological paradigm shifts there are negative consequences, which primarily will be addressed through dialogue and open communication with stakeholders and affected parties.

- Compliance for EURECA activities in ACCLAIM

  To ensure compliance in ACCLAIM projects, we impose on the partners of ACCLAIMS to do ethics self-assessment as part of the application process. Additionally, the implementation agreement will include requirements for the beneficiaries to comply with current data regulation directives as well as relevant EU legislations

5 APPENDIX A: ETHICS SELF – ASSESSMENT

European Commission - Research - Participants
Proposal Submission Forms

Proposal ID **738039** *Acronym* **EURECA**

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Does your research involve the use of human embryos?	○ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	○ Yes ◉ No	
2. HUMANS		**Page**
Does your research involve human participants?	○ Yes ◉ No	
Does your research involve physical interventions on the study participants?	○ Yes ◉ No	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	○ Yes ◉ No	
4. PERSONAL DATA (ii)		**Page**
Does your research involve personal data collection and/or processing?	○ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS (iii)		**Page**
Does your research involve animals?	○ Yes ◉ No	
6. THIRD COUNTRIES		**Page**
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	○ Yes ◉ No	
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? (v)	○ Yes ◉ No	
Do you plan to import any material from non-EU countries into the EU? *For data imports, please fill in also section 4.* *For imports concerning human cells or tissues, fill in also section 3.*	○ Yes ◉ No	
Do you plan to export any material from the EU to non-EU countries? *For data exports, please fill in also section 4.* *For exports concerning human cells or tissues, fill in also section 3.*	○ Yes ◉ No	
If your research involves low and/or lower middle income countries, are benefits-sharing action planned? (vii)	○ Yes ◉ No	

H2020-Cleansky-CFP.pdf Ver1.02 20151112 Page 16 of 18 Last saved 02/06/2016 00:31:39

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Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

European Commission - Research - Participants
Proposal Submission Forms

Proposal ID **738039** *Acronym* **EURECA**

Could the situation in the country put the individuals taking part in the research at risk?	○ Yes ◉ No	
7. ENVIRONMENT & HEALTH and SAFETY See legal references at the end of the section. (vi)		Page
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, please fill in also section 5.*	○ Yes ◉ No	
Does your research deal with endangered fauna and/or flora and/or protected areas?	○ Yes ◉ No	
Does your research involve the use of elements that may cause harm to humans, including research staff? *For research involving human participants, please fill in also section 2.*	○ Yes ◉ No	
8. DUAL USE (vii)		Page
Does your research have the potential for military applications?	○ Yes ◉ No	
9. MISUSE		Page
Does your research have the potential for malevolent/criminal/terrorist abuse?	○ Yes ◉ No	
10. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	○ Yes ◉ No	

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents. ☐

How to Complete your Ethics Self-Assessment

4 - Call specific questions

This proposal is being submitted by a consortium	○ Yes ◉ No
This proposal contains a legal entity which is a cluster	○ Yes ◉ No

The Cluster option shall be ticked only when the Cluster as such is an applicant and is applying with a validated and unique legal entity, which is duly able to enter into agreements with the JU. If the Cluster does not represent a unique and independent legal entity under national or EU law, the Consortium option should be selected by the applicant(s). See section II.4 of the CSJU rules for submission of proposals, selection, evaluation, review and award procedure.

Agreement on the access to the proposal by appointed representative of the CSJU Leaders

The proposal coordinator agrees in its capacity as legal authorized representative that access to this proposal, or part of it, may be given to the independent experts acting as evaluators and to the appointed representative of the members involved in the selection process, all of whom will be acting under a Confidentiality Agreement with the CSJU	☒

H2020-Cleansky-CFP.pdf Ver1.02 20151112 Page 17 of 18 Last saved 02/06/2016 00:31:39

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6 APPENDIX B: INFORMED CONSENT FORM DRAFT

The following topics must be adressed in the informed consent form:

- Purpose and plan of the research
- Nature and extent of any procedures
- Possible risks and benefits
- Legal rights and safeguards of participating citizens
- Right to withdraw consent at any time without discrimination or disadvantage
- Arrangements for responding to adverse events
- Confidentiality and privacy arrangements
- Arrangements for access to information
- Compensation arrangements (when applicable)
- Any foreseen future uses of the research results, data or materials, including commercial uses
- Source of funding for the research.

Signature of participant: _____ Date: _____

7 APPENDIX C: ETHICAL CONDUCT IN EURECA

The data will be collected and processed according to the European data protection law (95/46 / CE and 93/42 / EWG) and the European directive on clinical trials (2001/20 / CE) on good clinical practice in the conduct of clinical trials on Medicines for human use. The selected salient points including the ethical conduct of EURECA deals with the acts and directives mentioned above are summarized below.
The data will be collected based on their informed consent. Data on the characteristics of the relevant subjects, questionnaires, test data, etc. They will be coded numerically. The information hidden by the numerical code is accessible only to the principal investigators. If necessary, the subject can be linked to data by the principal investigators.
All data will be filed in coded form for as long as required by national legislation (post-project). When data is transferred from a EURECA project partner, this will only affect the encoded data. Furthermore, sensitive data will be protected with encryption. Only those involved in the analysis of the interest in the project access to coded data. Producers can use the data for research purposes, as inserted in a scientific context and conferences without the names and identity of the subjects.
All participants (candidates) will be informed in writing (and also verbally) of the purpose and nature of the experiment via an information form for the participants. After receiving a notice to sign an informed consent form. The main issues to be addressed are: the purpose and the research plan; Procedure Nature and extension of any; Possible risks and benefits; Positive judgment by the local ethics committee (if available at the presentation date); Legal rights and guarantees of participating citizens; Right to withdraw consent at any time without discrimination or disadvantages; Mode of response to adverse events; Confidentiality and privacy provisions; Devices for accessing information; Indemnity agreements (where applicable); Any future use of results, data or research materials, including commercial uses; Source of research funding.
Technical documentation (eg Investigational Medical, other documentation and technical documentation (eg Investigational Medical) Dossier on devices) where required, etc..

Safety issues

The scope of the project spans from human working in spaces shared with robots mounted on moveable platforms. Physical involvement of the humans will be considered for the evaluations of the trials.
Only informed and trained operators will be allowed to use the devices developed and deployed in EURECA. The trials may be realized in different countries hence laws, acts, and regulations of all the countries involved will be followed to the fullest. Risk analysis and mitigation will be performed before each test. The risk analysis of each task will be reported in D4.1 (Aug, 2019). As remark, the orocedures will be defined for each trial. Hubs involved in the trials (i.e., CNR laboratories, IFAM laboratories, Airburs facilities) will be in charge of safety issues and will make so that the measures set up are aligning with the regulations in Europe and in their countries. The following documents will be produced in addition to other documents that will be required by law and regulations in the respective country for ethical approval or otherwise. A document will be produced which will include identified risks and mitigation strategies that will be performed in order to eliminate the risks. The document will include a description of the equipment involved. The document will include will safety procedures that will be taken to ensure the safety of the participants. The document will also include hazards identified and how the participants will be informed/warned about the hazards. The usage of these equipment will be defined for instance in procedures describing the steps of the sequence and the action required by the participant. Test procedures will define total time taken for the test, persons involved in the test, safety precautions taken, and what is required of the participant.
Such documents will be provided for the actual final experiments, when also non-EURECA workers may b involved

Document no.	LPA-WP2.4.4.1-EURECA/D-3.1.
Document Title	D5.1 Ethics
Issue date	A03 – 25/07/2019

8 APPENDIX D: ETHICS ISSUE TRACKING

From internal websitie (https://itiacnr.sharepoint.com/Eureca/SitePages/Pagina%20iniziale.aspx)