

D8.2

H- Requirement No.2

Copies of opinions/approvals by ethics committees and/or competent authorities for research with humans

April 27th, 2022



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DOCUMENT SUMMARY INFORMATION

Grant Agreement No	101021957	Acronym	NIGHTINGALE
Full Title	Novel InteGrated toolkit for enhanced pre-Hospital life support and Triage IN challenGing And Large Emergencies		
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Deliverable	D8.2 H – Requirement No. 2		
Work Package	8		
Deliverable type	Ethics	Dissemination Level	Confidential
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Lead Beneficiary	ICCS		
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Reviewers	Itamar Ashkenazi (ESTES), Yael Vias Gvirsman (IDC)		
Security Assessment	<input checked="" type="checkbox"/> Passed	<input type="checkbox"/> Rejected	<input type="checkbox"/> Not Required
Status	<input type="checkbox"/> Draft	<input checked="" type="checkbox"/> Peer Reviewed	<input checked="" type="checkbox"/> Coordinator Accepted

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HISTORY OF CHANGES

Version	Date	Changes
0.1	07/03/2022	Initial version
0.2	22/03/2022	Version ready for QA review
0.3	11/04/2022	Internal review completed
0.4	20/04/2022	Internal reviewers' comments addressed
1.0	27/04/2022	Final version

PROJECT PARTNERS

No.	Logo	Partner	Short name	Country
1		INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS	ICCS	Greece
2		TOTALFORSVARETS FORSKNING SINSTITUT	FOI	Sweden
3		LEONARDO – SOCIETA PER AZIONI	LDO	Italy
4		C4CONTROLS LTD [TERMINATED]	C4C [TERMINATED]	UK [TERMINATED]
5		NETCOMPANY-INTRASOFT	INTRA	Luxembourg
6		INOV INSTITUTO DE ENGENHARIA DE SISTEMAS E COMPUTADORES, INOVACAO	INOV	Portugal
7		EXUS SOFTWARE MONOPROSOPI ETAIRIA PERIORISMENIS EVTHINIS	EXUS	Greece
8		UNIVERSITAT POLITECNICA DE VALENCIA	UPV	Spain
9		ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
10		DEVERYWARE	DW	France
11		PARTICLE SUMMARY	PARTICLE	Portugal
12		TREE TECHNOLOGY SA	TREE	Spain
13		EUROPAISCHE GESENLLSCHAFT FUR TRAUMA -UND AKUTCHIRURGIE - ESTES	ESTES	Austria
14		INTERNATIONAL MR MID ASSOCIATION	MR MID	Sweden
15		UNIVERSITA DEGLI STUDI DEL PIEMONTE ORIENTALE AMEDEO AVOGADRO	UPO	Italy
16		ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	APHP-SAMU	France
17		UNIVERSITA CATTOLICA DEL SACRO CUORE	UCSC	Italy
18		MINISTERO DELL' INTERNO	MININT	Italy
19		AZIENDA SANITARIA LOCALE N 2 SAVONESE	ASL2	Italy
20		MAGEN DAVID ADOM IN ISRAEL	MDA	Israel
21		CARR COMMUNICATIONS LIMITED	CCL	Ireland
22		ASSOCIAZIONE CITTADINANZATTIVA ONLUS	CA	Italy
23		INTERDISCIPLINARY CENTER (IDC) HERZLIYA	IDC	Israel
24		ASTRIAL GmbH	ASTRIAL	Germany

LIST OF ABBREVIATIONS

Abbreviation	Definition
DOA	Description of Action – Annex to the General Agreement
EAB	Ethics Advisory Board
FSXs	Field integration and testing & Full scale field validation in operational conditions
IEA	Independent Ethics Advisor
M1; M2...	Month 1; Month 2...
PO	Project Officer
SSXs	Field integration and testing in small scale deployments

Executive Summary

The scope of this deliverable is that of addressing ethics issues as indicated for D8.2 (the present deliverable) in the Description of Action, namely “copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans”.

The activities of the Project involving human research participants are present in four tasks.

T5.2 and T5.3 were assessed as requiring ethics committee approval/opinion

- T5.2: Field integration and testing in small scale deployments (SSXs)
- T5.3: Field integration and testing & Full-scale field validation in operational conditions (FSXs)

T5.4 and 5.5 were assessed as not requiring ethics committee approval

- T5.4: LITs, TTXs, SSTs, FSXs Knowledge capitalisation: Systematic Training, Evaluation and Lessons
- T5.5: User familiarisation on the operation of the tools

The outcome of the assessment is that for Tasks 5.2 and 5.3 approval from/opinion of an ethics committee is required on the basis of the participation of humans in the research activity. Tasks 5.4 and 5.5, on the other hand, have been assessed as not requiring ethics approval because the involvement of humans is limited to the participation of experts and stakeholders in evaluating results through documentation and eventually participating in workshops aimed at analysing the lessons learnt and in relevant training. In this sense, the only personal data collected will be data necessary for the organization of the events. The assessment results were proposed by the coordinator (ICCS) and T7.6 (Ethical, security and privacy office) Leader (UCSC) and discussed with the Ethics Advisory Board and the Independent Ethics Advisor.

The work leading to the documentation required by the ethics committees, at the time of writing, is still in a development phase and therefore the requests are not yet receivable by the ethics committees. As soon as documentation (e.g., the detailed exercise action plan) is available, the approvals will be submitted as an update to the deliverable. In the meanwhile, the responsible partners APHP-SAMU (France) and ASL2 (Italy) are addressing their respective ethics committees with a pre-information letter for which a template is attached.

In order to continuously monitor any evolutions of the workplan consolidated in the Description of Action and assess if any modifications of the plan, or newly introduced activities, may require ethics approval, a questionnaire to be administered to partners after M6 is provided (Annex 3).