End-User Driven Demo for CBRNe

Annual Report on Ethical and Legal Review of Selected Deliverables

Deliverable No.: D84.5
Issue: 1.0
Date: 14/08/2014
Contract No. 313077

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The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under Grant Agreement no. 313077

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Document Information and Approval status

Contract number:	313077		
Project acronym:	EDEN		
Project Co-ordinator:	BAE Systems		
Document Responsible Partner:	UCSC		
Document Type:	Report – Official Deliverable		
Document number:	EDEN-WP84-DEL84.5-v1		
Document Title:	1st Annual Report on Ethical and Legal Review of Selected Deliverables		
Document ID:	D84.5		
Classification:	Unclassified		
Contractual Date of Delivery:	31/08/2014	**Actual date of delivery**	14/08/2014
Filename:	EDEN-WP84-UCSC-D84.5-v1.pdf		
Status:	Released		
Approval status			
Document Manager	**Verification Authority:**		**Project approval**
UCSC	ESB		EDEN Project Manager

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Executive Summary

In EDEN the Ethical Monitoring activities, led by the Rome Catholic University (UCSC), are on-going throughout the whole duration of the project and aim at ensuring that EDEN research activities respect the highest ethical, privacy, and data protection standards set up at the European Union level.

Since the very beginning of the project, an Ethical Monitoring Plan (EMP) has been established, including all activities related to the ethical monitoring. The EMP is structured around six sections:

1. Overview of the Ethical Monitoring in EDEN
2. Guidance documents
3. WP-level Feedback Forms, Task-level Feedback Forms, Critical Incident Reporting Form
4. Ethical Monitoring of Demonstration Activities
5. Ethical Review of Selected Deliverables
6. Partners involved in WP84

The present report is the First Annual Report on the Ethical and Legal review of Selected Deliverables (T84.5) and refers to point n°5 above. For more information on the EMP, the reader should refer to D84.1 on Annual Report on the EDEN Ethical Monitoring Helpdesk.

The present report includes summaries and recommendations provided to the partners responsible for selected deliverables from an ethical perspective. It covers the ethical review of deliverables which have been submitted during the 1st year (since September 2013 to August 2014).

Ethically relevant deliverables have been selected by partners involved in T84.5 on the basis of a possibility of:

- Potentially problematic processing of personal data;
- Research involving subject or volunteers;
- Development of tools potentially raising ethical issues;
- Significant interaction or communication with public.

Deliverables which are likely to touch upon at least one of the above mentioned issues, have been identified as requiring ethical monitoring.

In Year 1, the partner responsible for the ethical monitoring reviewed five deliverables. Three of them were related to the development of the scenarios for the demonstrations events, and the other two provided details on the general methodology and plans for the Demos. From an ethical perspective, the review identified two main issues which deserve special attention.
The first is related to the *development of the scenarios*, and refers to the importance of taking into account the ethical and legal dimensions of the *distinction between non-intentional / intentional incidents*, and related *safety / defence strategies*, the latter presumably involving intention detection and surveillance technologies targeting human beings (and not only objects). The second issue which emerged from the ethical monitoring is related to the *Demos organisation* and refers to the need to carefully monitor research activities carried out in these WPs, particularly from the "*research ethics*" and "*data protection*" perspectives: *informed consent* and *protection of volunteers* are key aspects to be considered.

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Partners Involved in Document

No	Partner	Short name	Check if involved
1	BAE Systems	BAES	
2	EADS Astrium	AST	
3	FFI	FFI	
4	Tecnoalimenti	TCA	
5	SELEX ES	SES	
6	SAMU	SAMU	
7	Main School of Fire Service	SGSP	
8	CSSC	CSSC	
9	Astri Polska	APL	
10	Istituto Affari Internazionali	IAI	
11	CBRNE LTD	CBRNELTD	X
12	UCL	UCL	
13	LDI	LDI2	
14	Fraunhofer	FhG EMI	
14	Fraunhofer	FhG INT	
14	Fraunhofer	FhG ICT	
15	VTT	VTT	
16	FRS	FRS	
17	Indra	IND	
18	INERIS	INR	
19	SICPA	SIC	
20	MDA	MDA	
21	PIAP	PIAP	
22	Hotzone	HZS	
23	ENEA	ENEA	
24	Nucletudes	NUC	
24	OMNIDATA S.A	OMN	
26	University of the Basque Country	UPV/EHU	X
27	University of Reading	UREAD	
28	Bruker UK	BRU	
29	LDIAMON	LDIAMON	
30	Microfluidic	MCG	
31	Robert Koch	RKI	
32	EU-VRI	EU-VRI	
33	Space Research Center	SRC	
34	AINIA	AINIA	
35	UCSC	UCSC	X
36	CBRNE Centre	UMU	

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CONTENTS

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LIST OF ABBREVIATIONS

CBRNe	Chemical, Biological, Radiological, Nuclear and Explosive
EEAB	EDEN Ethical Advisory Board
EDEN	End user driven Demo for CBRNe
ERD	Ethical Review Document
ERF	Ethical Review Form
ToT	Toolbox of Toolboxes
WP	Work Package

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1 INTRODUCTION

The EDEN consortium is aware that research activities have the potential to raise critical ethical and legal issues and is committed to adhere to the highest ethical and legal standards, as recognized at the European Union level. The ethical and legal issues raised by research and development activities must be accurately identified and addressed throughout the whole duration of the project. This is the objective of the ethical monitoring (WP84).

The ethical monitoring of the project is carried out by the *EDEN Ethical Monitoring Helpdesk*, which is led by the Rome Catholic University (UCSC) through WP84, with the support of CBRNE Ltd (in relation to societal and communicational aspects), UPV/EHU (with respect to legal issues), and the project's Ethical Advisory Board (EEAB, see D11.6 First Annual Report on the Ethical Advisory Board for further details).

In accordance with EDEN DoW, the Ethical Monitoring breaks down into three main activities, which correspond to specific tasks in WP84, as follows:

- Ethical monitoring of WPs, Tasks and tools development (T84.1)
- Ethical monitoring of Demonstration Activities (T 84.2, T84.3, T84.4)
- Ethical monitoring of Selected Deliverables (T84.5)

The present deliverable is the 1st Annual Report on the Ethical Review of Selected Deliverables and refers to Task 84.5 above. It includes summaries and recommendations provided to the partners responsible for deliverables which have been selected as "ethically sensitive". It covers the ethical review of deliverables submitted during the project's 1st year, since September 2013 to August 2014.

It has to be mentioned that a change occurred in WP84 workplan during the first year. From m1 to m6 (September 2013 – February 2014) the Leader of WP84 (and of T84.5) has been the Centre for Science, Society and Citizenship (CSSC). After CSSC withdrawal from the EDEN project in March 2014, the ethical monitoring, along with the responsibility to review deliverables from an ethical perspective, was allocated to the Rome Catholic University (UCSC).

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1.1 Scope of Project

The main purpose of EDEN is to:

- Shorten time to response (after an event occurs)
- Improving mass gathering/events security
- Enhancing the protection of sensitive or critical infrastructures
- Achieving a European lead in CBRNE sampling, detection, proficiency testing and forensics
- Boosting the EU civilian CBRNE market
- Reinforcing technological, societal and psychological resilience of the EU society

These aims will be realised with the EDEN Toolbox of Toolboxes approach and checked and improved throughout the demonstrations.

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1.2 Purpose of document

The purpose of this document is:

- To provide details on the process of Ethical Review of Selected Deliverables (section 2)
- To provide summaries of the deliverables which have been reviewed during Year 1 (from September 2013 to August 2014), and to report on the results of the ethical monitoring of these deliverables (section 3)

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1.2.1 Scope of the document

This document reports on the activities carried out in the scope of task 84.5, Ethical and Legal Review of Selected Deliverables.

For general information on the Ethical Monitoring Plan established in WP84, the reader should refer to D84.1 Annual Report on the EDEN Ethical Helpdesk. D11.6 on Annual Report of the Ethics Advisory Board provides details on the ethical monitoring activities carried out by the project independent advisory board.

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2 THE PROCESS OF ETHICAL REVIEW OF SELECTED DELIVERABLES

In October 2013, after the project Kick Off Meeting, the partner responsible for the ethical monitoring (CSSC, at that time) analysed the EDEN DoW in order to identify those deliverables that were considered to be likely to raise particular issues from the ethical perspective.

The **List of Ethically Relevant Deliverables** (see Annex I) was compiled by CSSC, and approved by the other partners contributing to WP84.5 (CBFRNE Ltd and UPV/EHU) and by the project coordinator. Ethically relevant deliverables were selected on the basis of a possibility of:

- Potentially problematic processing of personal data
- Research involving subject or volunteers
- Development of tools potentially raising ethical issues
- Significant interaction or communication with public

It has to be noted that the list of ethically relevant deliverables is open to amendment as necessary. Moreover, every task in EDEN is independently subject to internal ethical monitoring, even if deliverables associated with that task have not been selected as “ethically relevant”. This monitoring takes place through Task 84.1 (Virtual Helpdesk), through which UCSC (and contributing partners) receive feedback from partners (WP- and task-leaders) on their proposed research activities.

CSSC agreed with the coordinator that ethically relevant deliverables would have received ethical review in parallel to the procedure of scientific quality review, which is carried out by the EDEN Steering Board. Likewise the scientific quality review, the outcomes of the ethical review are available within two weeks of receipt of the deliverable, and are directly transferred to the deliverable owner.

In April 2014, when UCSC took over the responsibility of ethical monitoring, a detailed **Ethical Review Form** (ERF, see Annex II) was prepared.

The ERF consists of two parts. The first part is used to identify the deliverable, its author or authors and the author of the review, and includes a section were key recommendations are provided.

The second part consists of specific ethical questions. The questionnaire includes the most critical “areas of ethical concern”, which may be touched upon by research activities. The key “areas of ethical concern”, included in EDEN ERF, are:

- Research on Human Embryo/Foetus
- Research on Humans
- Vulnerable Groups
- Informed Consent
- Privacy
- Data Collection
- Research involving “International Cooperation Partner Country” (ICPC)
- Dual Use

Research activities carried out in EDEN are expected to raise concerns particularly in relation to the “research on humans”, “informed consent”, “privacy” and the “data collection” areas.

UCSC developed a detailed questionnaire for each area of ethical concern. Many questions are taken from the Section No. 4 (Ethical Issues) of the Ethic Issues Table (Page 208) in the

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Part B of the EDEN project. Additional questions, targeted to the EDEN research field, were developed by UCSC.

Deliverables submitted to the ethical monitoring are reviewed on the basis of the ERF. The results of the ethical review of selected deliverables are recorded in a specific **Ethical Review Document** (ERDXX), which is transmitted to the owner of the deliverable so that comments and recommendations from the ethical review are integrated in the document.

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3 ETHICAL REVIEW OF SELECTED DELIVERABLES / YEAR 1

Since April 2014, UCSC reviewed five deliverables which were previously selected as “ethically sensitive”, and compiled an Ethical Review Document for any of these deliverables.

For the time being, the deliverables reviewed and the corresponding ERD have been:

- D 23.3, Constraints and Scenario for WP40 (Deliverable owner: TCA) – ERD01
- D 51.1, General Methodology and Plan (INR) – ERD02
- D 61.1, General Plan approved by Preliminary Review (SGSP) – ERD03
- D 23.4, Constraints and Scenario for WP50 (FFI) – ERD05
- D 23.5, Constraints and Scenario for WP60 (FFI) – ERD06

The paragraphs below present a synthesis of the deliverables' Executive Summaries and of the key recommendations which resulted from the ethical review.

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3.1 D23.3 Constraints and scenarios for WP40

D23.3 presents the scenarios developed for the food demonstrations in WP40. The scenarios are based on two voluntary B and C contamination of the food chain (scenario 1 and 3) and one accidental contamination (scenario 2). According to the deliverable Executive Summary, "the EDEN food scenarios were designed on the basis of the end-user needs, collected in the D22.1, of a vulnerability assessment of model food matrices and of the identification of the most attractive points for a potential attack. The food scenarios have been designed on a preliminary selection of model food production processes taking in account the identification of the levels/steps that could represent a threat against C and B intentional contamination. As final result of this analysis, the *processed meat* and the *sugar production* chains have been selected for the definition of potential attack scenarios".

The key recommendations which resulted from the ethical review of this deliverable have been:

- to include also the consideration that the **distinction between unintentional / intentional contamination** (and related distinction between **food safety** and **food defence** strategies), in addition to technical aspects, **has an ethical / legal dimension as well** (with respect to, e.g., different ethical issues raised by different prevention strategies). In particular, it was suggested to integrate the consideration that **classifying categories of individuals** is more legally and ethically sensitive than, for instance, classifying categories of hazards;
- it was suggested to mention that in EDEN, WP80 will aim at **integrating ethical, societal and communicational considerations** into the methods which are commonly used to assess the different impacts of a CBRNe crisis.

The complete ERD01 for D23.3 is included as Annex III.

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3.2 D51.1 General Methodology and Plan

D51.1 report presents the general methodology and demonstration action plan for the multi-chemical full-scale demonstrations and pre-demonstration for the TIC scenario as for the medical scenarios.

The key recommendations provided from the ethical perspective on this deliverable are included in ERD02 (Annex IV).

Broadly speaking, the ERD provides insights on how to integrate the ethical monitoring related tasks into the Demos organisation. As an example, in the ERD it is recommended that, among the "*Demo assessment criteria*", the "*adherence to the highest EU Ethical and Legal Standards*" (to be assessed by WP84) is included. It was also suggested that any "phase" of the Demo organisation should correspond to a specific input from the ethical monitoring: during the "initial phase", a booklet will be prepared on the key ethical issues raised by the Demo; during the Demo event, a set of interview will be carried out as "in-field monitoring"; during the assessment phase, the Demo will be evaluated on the basis of ethical criteria.

In addition, the most pressing ethical issues to be considered in this phase have been identified as follows:

- To provide clarification on the mentioned "real incidents" that may occur during the demonstration and related risk mitigation strategy;
- To clarify which Data Collection or Ethical Approvals have been sought from competent authorities and in which countries. Copies of these approvals will have to be submitted to the European Commission through D11.2;
- To clarify if the suggestions provided above are in line with the expectations for the "ethical monitoring" of this demonstration event (in particular, the request to identify the person who will be responsible to liaise with the Ethical Monitoring Officer).

The partner responsible for the WP50 Demo (INR) will continue working in strict collaboration with the partner responsible for the ethical monitoring (UCSC) in the scope of Task 84.3 Multi-C Demo Ethical Monitoring.

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3.3 D61.1 General Plan Approved by Preliminary Review

D61.1 on the General Plan approved by Preliminary Review presents the details of all organisational aspects on preparation and conducting process of series of 6 radiological and nuclear (RN) demonstrations scheduled in Work Package 60 (WP60) which are aimed to validate EDEN Project's RN Toolbox and its separate tools. It is also describing schemes of radiological and nuclear safety system of countries where demonstrations activities will take place (Poland, Italy, Ukraine) together with European Union and global systems.

The ethical review of this deliverable has not detected any particularly critical issue at this stage. The detailed ERD is available as Annex V.

The partner responsible for the WP60 Demo (SGSP) will continue working in strict collaboration with the partner responsible for the ethical monitoring (UCSC) in the scope of Task 84.4 RN Demo Ethical Monitoring.

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3.4 D11.2 Data Protection Procedures and Approvals

The Ethics Review Document (ERD04) for D11.2 Data Protection Procedures and Approvals is not available yet, since at the present date (July 29th 2014) the Deliverable has not been submitted to the Ethical Monitoring. The related ERD will be discussed and included in the Annual Report of Ethical Review of Selected Deliverables covering Year 2 (from September 2014 to August 2015).

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3.5 D23.4 Constraints and Scenarios for WP50

D23.4 report presents scenarios and scenario constraints for the EDEN multi-C demonstrations. The five scenarios are C1: Petroleum refinery in Belgium, C2: Fertiliser facility in Romania, C3: Chemical site in France, C4: Sarin release in building ventilation system and C5: Bomb blast with suspected sulphur mustard. C1, C2 and C3 will be demonstrated in actual locations with operative end-users in collaboration with the site owners and national authorities. C4 and C5 will be conducted in one table-top demonstration involving different end-users including operative and medical personnel.

The Ethical Review of D23.4 has not detected any particularly critical ethical issue. The detailed ERD05 is available as Annex VI.

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3.6 D23.5 Constraints and Scenarios for WP60

D23.4 presents scenarios and scenario constraints for the EDEN RN demonstrations. The nine scenarios are RN1: Dirty bomb field exercise (large and small scale), RN2: Handling of major nuclear facility accident, RN3: Terrorist attack on virtual nuclear facility, RN4.1: Smuggling of radiological materials, RN4.2: Dirty bomb threat analysis, RN4.3: Faulty reactor fuel rod discovered by optical technique, RN5.1: Operational fault in nuclear reactor, RN5.2: Rescue and decontamination effort and RN5.3: Tabletop exercise on European-level crisis management. Some demonstrations will be in the actual locations with operative end-users in collaboration with the site owners and national authorities. Others will be conducted in table top demonstrations involving different end-users.

The Ethical Review of D23.5 has not detected any particularly critical ethical issue. The detailed ERD06 is available as Annex VII.

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3.7 The specific ERD for WP83.3

Originally it was not foreseen to include any of the WP80 deliverables in the list of "Ethically sensitive deliverables", in consideration of the fact that these activities are carried out by partners who are expert in ethical, legal and societal issues. However, the partner responsible for the ethical monitoring informed all WP80 contributing partners about the availability to provide support in relation to any ethical issues which may emerge in WP80 research activities.

This was the case for T83.3. In the scope of this task, a survey is being carried out in order to analyse the likely public perception of EDEN tools. In June 2014, CBRNE Ltd, as leader of WP83, contacted UCSC and asked to evaluate a set of documents prepared for this survey. These documents were the "Information Sheet", "Consent Form" and "Questionnaire". UCSC prepared a specific ERD (Annex n°VIII), including the following comments:

- **Comments on the "Information sheet" and the "Consent form"**

The reassurance of complete anonymity of the questionnaire and the request to sign the consent form may be in contradiction. Considering that, in order to carry out the research, you should seek the participants' consent, you might make the consent form and the completed questionnaires only *indirectly linkable* (through, for instance, a "number" as the same identifier of both documents) to guarantee the respondent's anonymity. We suggest that you identify a "data controller" within your team, who will be responsible for the collection of personal data, and will be able to link the consent form with the related questionnaire, only if need be (e.g., an audit).

- **Comments on the Questionnaire**

We suggest to include, if possible, an additional question on the respondent's opinion on the impact of surveillance technologies on human rights (e.g., privacy, data protection, fundamental freedoms, etc...). This may help to evaluate not only the perceived efficacy of the technologies, but also the perceived effect on human rights protection. We suggest to include a question about the kind of expert you are interviewing (academic expert, policy maker, first responder, etc).

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4 CONCLUSIONS

In Year 1, the partner responsible for the ethical monitoring reviewed five deliverables. Three of them were related to the development of the scenarios for the demonstrations events, and the other two provided details on the general methodology and plans for the Demos.

From an ethical perspective, the review identified two main issues which deserve special attention.

The first is related to the *development of the scenarios*, and refers to the importance of taking into account the ethical and legal dimensions of the *distinction between non-intentional / intentional incidents*, and related *safety / defence strategies*, the latter presumably involving intention detection and surveillance technologies targeting human beings (and not only objects).

The second issue which emerged from the ethical monitoring is related to the *Demos organisation* and refers to the need to carefully monitor research activities carried out in these WPs, particularly from the "*research ethics*" and "*data protection*" perspectives: *informed consent* and *protection of volunteers* are key aspects to be considered.

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5 REFERENCES

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6 ANNEXES

Annex n°1: List of Ethically Relevant Deliverables
Annex n°2: Ethics Review Form (ERF)
Annex n°3: Ethics Review Document 1 (ERD01 – D23.3)
Annex n°4: Ethics Review Document 2 (ERD02 – D51.1)
Annex n°5: Ethics Review Document 3 (ERD03 – D61.1)
Annex n°6: Ethics Review Document 5 (ERD05 – D23.4)
Annex n°7: Ethics Review Document 6 (ERD06 – D23.5)
Annex n°8: Ethical Review of EDEN T83.1 on Public Perception

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DELIVERABLES FOR ETHICAL MONITORING

WP84 > Task 84.5 (CSSC)

The EDEN DOW describes Task 84.5 as follows.

T84.5 Ethical Review of Selected Project Deliverables
(Leader: CSSC; contributors: CBRN, UPV/EHU)

This task involves the internal ethical and legal review of relevant EDEN deliverables and documentation. Relevant deliverables to be decided at EDEN Kick Off Meeting. The task will take input from WP31, specifically the "ethical index" there developed by CSSC. UPV/EHU will provide monitoring from the legal perspective. The key contribution to this WP is systematic review processes and provision of timely comment. CBRN will also be able to support the ranking of any comments following review to support a hierarchical management of issues. CBRNELTD will assure that the rights of the general public are maintained and safeguarded as far as possible in the context of different levels of risk management cycle and with regard to the "Ethical Index"; will contribute to the development of ethical booklets and to the Annual Report on Ethical Review of Selected Deliverables.

As leader of T84.5, CSSC has identified the deliverables listed in the table below as requiring monitoring. Deliverables have been selected on the basis of a possibility of:

- potentially problematic processing of personal data;
- research involving human research subjects or volunteers;
- development of tools potentially raising ethical issues;
- involvement of the public or public communication;

It should be noted that every task in EDEN is independently subject to internal ethical monitoring, even if deliverables associated with that task are not listed in the table below. This monitoring takes place through Task 84.1 (Virtual Helpdesk), through which CSSC (and contributing partners) receive feedback from partners (WP- and task-leaders) on their proposed research activities. It should be further noted that the list below is potential open to amendment at a later date.

WP	Del. No.	Deliverable Title	Lead	Partner	Diss. Level	Due	Month	Year
11	11.2	EDEN Data Collection Procedures and Approvals	1	BAES	PP	12	August	2014
21	21.1	End-user Needs for CBRNE Demos and EDEN ToT Report	3	FFI	Rest. UE	7	March	2014
22	22.2	Gap Analysis Report	3	FFI	Conf. UE	8	April	2014
23	23.3	Constraints and Scenario for WP40	4	TCA	Rest. UE	9	May	2014
23	23.4	Constraints and Scenario for WP50	3	FFI	Rest. UE	12	August	2014
23	23.5	Constraints and Scenario for WP60	3	FFI	Rest. UE	12	August	2014
31	31.1	EDEN Store Design and Core Elements	2	AST	PP	32	April	2016
33	33.1	EDEN Store new Common Tools REport	14	Fraunhofer	RE	32	April	2016
42	42.1	Report on Food Demo	4	TCS	Conf. UE	34	June	2016
42	42.2	Assessment of the Demo Test	3	FFI	Conf. UE	36	August	2016
51	51.1	General Methodology and Plan	18	INR	Rest. UE	10	June	2014
53	53.3	Final Animation Plan	18	INR	Rest. UE	33	May	2016
54	54.4	Report on Initial Field Exercise	18	INR	Rest. UE	19	March	2015
54	54.5	Interim Test Report	18	INR	Rest. UE	26	October	2015
54	54.6	Final Report on Test Service	18	INR	Conf. UE	34	June	2016
54	54.7	Evaluation Report on Large-Scale Multi-C Demonstration	18	INR	Rest. UE	34	June	2016
61	61.1	General Plan Approved by Preliminary Review	7	SGSP	Rest. UE	10	June	2014
63	63.3	Report on Field Initial Exercise	7	SGSP	Rest. UE	19	March	2015
63	63.4	Report on Table-top Exercise and Simulation for Virtual Environment	7	SGSP	Rest. UE	29	Jan	2016
63	63.5	Report on thematic Demonstrations	7	SGSP	Conf. UE	28	Dec	2015
64	64.6	Interim Report from the Test Service	33	SRC	Rest. UE	25	Sept	2015
64	64.7	Final Report from the Test Service	33	SRC	Conf. UE	34	June	2016
65	65.8	Evaluation Report of the RN Demonstration	7	SGSP	Conf. UE	34	June	2016
72	72.2	EDEN Resilience and Evaluation Tools	11	CBRNELTD	Conf. UE	8	April	2014
73	73.4	EDEN Technical, Society and Capability Assessment	1	BAES	RE	35	July	2016
73	73.6	EDEN Recommendations, Way Forward and Roadmaps	1	BAES	RE	36	Aug	2016
74	74.9	Policy Briefing for Public Procurement in CBRNe	32	EU-Vri	RE	34	June	2016
91	91.1	Dissemination Plan	9	APL	PU	3	Nov	2013
91	91.15	Installation of Discussion and Promotion Groups	9	APL	PU	3	Nov	2013
91	91.17	Report on Fulfilment of Dissemination Plan	9	APL	RE	36	Aug	2016

Annex n°2: Ethics Review Form (ERF)

EDEN DELIVERABLES ETHICS REVIEW FORM (ERF)

This form records the results of the Ethical Review of EDEN ___ (insert the deliverable number and title) in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.
Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Document under review	
Author of the document	
Date of submission	
Reviewer	
Date of review	
Recommendations	
Review summary	**CRITERION 1) Ethical Issues** Does the document touch on any recognizable ethical issue? If the answer is YES, you should complete the tables below. **Research on Human Embryo/Foetus:**

Question	NO	YES	Deliverable Page
Does the proposed research involve human Embryos?			
Does the proposed research involve human Foetal Tissues/Cells?			
Does the proposed research involve human Embryonic Stem Cells (hESCs)?			
Does the proposed research on human Embryonic Stem Cells involve cells in culture?			
Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?			

Research on Humans:

Question	NO	YES	Deliverable Page
Does the proposed research involve adult healthy volunteers?			
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?			
Does the proposed research involve patients?			
Does the proposed research involve Human genetic material or biological samples?			
Does the proposed research involve personal data collection?			
Are the rights related to physical security and integrity[1] involved?			
Are the rights related to the basic necessities of life[2] involved?			

[1] e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.
[2] e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

Does the proposed research touch upon the principle of non-discrimination?			
Is research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?			
Are beneficence (doing good), non-maleficence (preventing or mitigating harm), personal dignity and respect of autonomy taken into account in the research?			
Are third party organizations involved that might have influence on the research activities as well as on the ethical and legal conduct?			

Vulnerable Groups:

Question	NO	YES	Deliverable Page
Does the proposed research involve vulnerable groups?			
Is a definition of *vulnerability* provided?			
Is there a categorization of groups by vulnerability?			
Does the research reflect the fact that vulnerable groups have particular needs?			
Are human rights[3] be used as a framework to examine the effect of the research on vulnerable groups?			

Informed Consent:

Question	NO	YES	Note
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?			
Will the volunteers receive written documentation of the same?			
Will the briefings and documentation be available in a language in which the subject is at home?			
Will briefings and documentation be free from jargon and readily accessible to non-specialists?			
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?			
Will volunteers be fully briefed as to their right to withdraw?			
Will volunteers be briefed as to the possible risks or benefits of participation?			
Will volunteers fully understand what they are required to do?			
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?			
Where volunteers are introduced to the project through their employers (e.g. emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?			
Will volunteers have access to details of			

[3]Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

insurance coverage and medical provision relevant to the demonstration event?			
Will volunteers be given the names of responsible project members, including an assigned data controller?			
Will volunteers' understanding be checked in informal interviews?			
Will the informed consent and "opting-in" be documented?			

Privacy:

Question	NO	YES	Deliverable Page
Does the proposed research involve processing of genetic information or personal data[4]?			
Does the research involved physical or psychological integrity?			
Does the proposed research involve tracking the location or observation of people?			
Does the research involve the use of profiling technologies?			
Does the research identify persons who are authorized to have access to the data collected and/or to surveillance and profiling technologies?			
Is any official national or international guidelines on protecting privacy mentioned?			
Is there an established Data Protection Authority issuing procedures / standards that research must follow before performing tests with human participants and their personal / private data?			
Is sensitive information recorded?			
Is the organization insured against risks as a result of breach of privacy and safety?			

Data Collection:

Question	NO	YES	Deliverable Page
Are data gathered from individuals in accordance with relevant EU and national legal standards?			
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?			
Are volunteers informed that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?			
Does the research identify persons who are authorized to have access to the data collected and/or to surveillance and profiling technologies?			
Is any official national or international guidelines on protecting privacy mentioned?			

Research on Animals:

[4] e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

Question	NO	YES	Deliverable Page
Does the proposed research involve research on animals?			
Are those animals transgenic small laboratory animals?			
Are those animals transgenic farm animals?			
Are those animals non-human primates?			
Are those animals cloned farm animals?			

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?			
Is any material used in the research[5]: a) Collected in any of the ICPC?			
b) Exported to any other country (including ICPC and EU Member States)?			

Dual Use:

Question	NO	YES	Deliverable Page
Does the research have direct military use?			
Does the research have the potential for terrorist abuse?			

[5] e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

Annex n°3: Ethics Review Document 1 (ERD01 – D23.3)

ETHICS REVIEW DOCUMENT ERD01

This form records the results of the Ethical Review of **EDEN D23.3 Constraints and scenarios for WP40 (ERD01)** in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Document under review	D23.3 Constraints and scenarios for WP40
Author of the document	Tecnoalimenti SCpA (TCA)
Date of submission	May 15th 2014
Reviewer	Università Cattolica del Sacro Cuore (UCSC)
Date of review	May 26th 2014
Recommendations	The report presents the scenarios developed for the food demonstrations in WP40. The scenarios are based on two voluntary B and C contamination of the food chain (scenario 1 and 3) and one accidental contamination (scenario 2). However, also scenario C1 (page 62), which was meant to be caused by an industrial accident, has an **intentional origin**. It would be important to consider also non-intentional events, which may have the same serious consequences as a voluntary contamination. In scenario C2, it is strongly suggested to delete the detail about the imaginary environmental activist group being "opposed to GM" (page 67 – mentioning this does not represent an added-value for the scenario). Generally speaking, the **distinction between unintentional / intentional contamination** (and related distinction between **food safety** and **food defence** strategies), in addition to technical aspects, has an ethical / legal dimension as well (with respect to, e.g., different ethical issues raised in different scenarios). This could be briefly pointed out in the report, and reference could be made with EDEN WP80 where these aspects will be dealt with in depth. In line with this consideration, it is recommended that it is explained from where the "classification of food aggressors" (pag. 12) is taken. **Classifying categories of individuals** is more legally and ethically sensitive than, for instance, classifying categories of hazards (page 13). In addition, the "intention detection" or the "abnormal behaviour" approach, even if much research is currently being carried out also in Europe on this, are not self-evident. It is therefore important to be rigorous with providing references for any definition/classification of categories of humans or human behaviour. In section 2.3.1 the **CARVER+Shock** methods is described. The "Shock" component includes not only economic and psychological impacts, but has ethical (in relation to, e.g., media coverage and journalists' codes of conduct), societal (es. Potential impact on specific groups) and communicational (e.g., trust in public authorities, transparency of their communications) dimensions. Integrating ethical, societal and communicational considerations into this method may deeply improve the response and recovery efforts; it would be good to mention that EDEN aims exactly at achieving this through the research carried out in WP80. The **shift to "surveillance" points** may also raise some general concerns about its ethical implications when the surveillance target is a human and

	not an object. This does not seem the case for WP40 scenarios; WP50 and WP60 scenarios are more likely to raise this type of concern.
Review summary	**CRITERION 1) Ethical Issues** Does the document touch on any recognizable ethical issue? If the answer is YES, you can continue **Research on Human Embryo/Foetus:**

Question	NO	YES	Deliverable Page
Does the proposed research involve human Embryos?	X		
Does the proposed research involve human Foetal Tissues/Cells?	X		
Does the proposed research involve human Embryonic Stem Cells (hESCs)?	X		
Does the proposed research on human Embryonic Stem Cells involve cells in culture?	X		
Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?	X		

Research on Humans:

Question	NO	YES	Deliverable Page
Does the proposed research involve adult healthy volunteers?	X		
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?	X		
Does the proposed research involve patients?	X		
Does the proposed research involve Human genetic material or biological samples?	X		
Does the proposed research involve personal data collection?	X		
Are the rights related to physical security and integrity[6] involved? X			
Are the rights related to the basic necessities of life[7] involved? X			
Does the proposed research touch upon the principle of non-discrimination?		X	See recommendations
Is research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	n.a.		
Are beneficence (doing good), non-maleficence (preventing or mitigating	n.a.		

[6]e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.

[7]e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

harm), personal dignity and respect of autonomy taken into account in the research?			
Are third party organizations involved that might have influence on the research activities as well as on the ethical and legal conduct?	X		

Vulnerable Groups:

Question	NO	YES	Deliverable Page
Does the proposed research involve vulnerable groups?		X	
Is a definition of *vulnerability* provided?	X		
Is there a categorization of groups by vulnerability?	X		
Does the research reflect the fact that vulnerable groups have particular needs?	X		
Are human rights[8] be used as a framework to examine the effect of the research on vulnerable groups? X			

Informed Consent:

Question	NO	YES	Note (if No)
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?	N.A.		
Will the volunteers receive written documentation of the same?	N.A.		
Will the briefings and documentation be available in a language in which the subject is at home?	N.A		
Will briefings and documentation be free from jargon and readily accessible to non-specialists?	N.A.		
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?	N.A		
Will volunteers be fully briefed as to their right to withdraw?	N.A		
Will volunteers be briefed as to the possible risks or benefits of participation?	N.A.		
Will volunteers fully understand what they are required to do?	N.A.		
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?	N.A		
Where volunteers are introduced to the project through their employers (e.g.	N.A.		

[8]Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?			
Will volunteers have access to details of insurance coverage and medical provision relevant to the demonstration event?	N.A.		
Will volunteers be given the names of responsible project members, including an assigned data controller?	N.A.		
Will volunteers' understanding be checked in informal interviews?	N.A.		
Will the informed consent and "opting-in" be documented?	N.A.		

Privacy:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve processing of genetic information or personal data[9]? X			
Does the proposed research involve tracking the location or observation of people?	X		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	X		
Do you clarify to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	X		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	X		
Do you follow written procedures for protecting privacy?	X		
Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?	X		
Is private information recorded?	X		
Is your organization insured	X		

[9] e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

against risks as a result of breach of privacy and safety?			

Data Collection:

Question	NO	YES	(Note if NO)
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	N.A.		
Are data gathered from individuals in accordance with relevant EU and national legal standards?	N.A		
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?	N.A		
If data aren't gathered from individuals in accordance with relevant EU and national legal standards, later will be stored securely?	N.A		
Do you clarify to the people that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	N.A		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	N.A		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	N.A.		
Do you follow written procedures for protecting privacy?	N.A		
Is private information recorded?	N.A		

Research on Animals:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve research on animals?	X		
Are those animals transgenic small laboratory	X		

animals?			
Are those animals transgenic farm animals?	X		
Are those animals non-human primates?	X		
Are those animals cloned farm animals?	X		

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page (if YES)
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?	X		
Is any material used in the research[10]: a) Collected in any of the ICPC?	X		
b) Exported to any other country (including ICPC and EU Member States)?	X		

Dual Use:

Question	NO	YES	Page (if YES)
Does the proposed research have direct military use?	X		
Does the proposed research have the potential for terrorist abuse?	X		

[10] e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

Annex N°4: Ethics Review Document 2 (ERD02 – D51.1)

ETHICS REVIEW DOCUMENT ERD02

This form records the results of the Ethical Review of **D51.1 General Methodology and Plan**, in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Document under review	D51.1 General Methodology and plan
Author of the document	Ineris –
Date of submission	June 9th 2014
Reviewer	UCSC – Silvia Venier / Emma Traisci
Date of review	June 18th 2014
Recommendations	**Scope of the Ethics Review Form** 1 D51.1 presents an overview of the General Methodology and Plan for the multi-C Demo. This review form points out a set of key recommendations to be included in the deliverable, in order to confirm that, since the planning phase, WP50 research is being carried out in line with the EU highest ethical and legal standards. 2 In addition to the recommendations presented below, it is highly recommended that responsible partners read carefully the two **Info Sheet** on **Research Ethics** and **Data Protection** which are available on the "Ethics" section of the EDEN website. **Recommendations** The main ethical aspects touched by the deliverables are as follows: **Section 2.2 (page 16):** Ethical and legal questions should be mentioned as well (for instance, it could be mentioned that we are aware that the type of crisis analysed in WP50 also raises difficult ethical and legal questions. These questions are being addressed in the scope of WP80 interaction between WP50 and WP80 is guaranteed by WP84 on the Ethical Monitoring). **Section 3.1 (page 20)**: it could be added that one objective is "to complete research in line with the highest ethical and legal standards. This will be guaranteed by the collaboration between WP50 and WP84 on the ethical monitoring". **Section 3.1.1 (page 21):** it seems that in the "prevention phase" only "malevolent acts" are mentioned. Is this the focus of EDEN (and in particular of WP50), or should the solutions developed be targeted also to "CBRN incidents"? As already mentioned in the Ethics Review Form of D23.3 (Constraints and Scenarios for WP40), the distinction between UNINTENTIONAL / INTENTIONAL crisis, in additional to technical aspects, has strong ethical and legal implications. **Section 3.2 (page 25):** it is recommended that, among the "Demo assessment criteria", the "adherence to the highest EU Ethical and Legal Standards" (to be assessed by WP84) is included. **Section 4.1 (page 29):** it could be mentioned that any "phase" will correspond to a specific input from the ethical monitoring, which will be provided by WP84.3: during the "initial phase", a booklet will be prepared on the key ethical issues raised by the Demo; during the Demo event, a set of interview will be carried out as "in-field monitoring"; during the assessment phase, the Demo will be evaluated on the basis of ethical criteria. **Section 4.2.1 (page 32):** May we include, among the responsibilities of one of the coordinators/officers, the responsibility to liaise with the "Ethical

Monitoring Officer" (i.e., a person member of the UCSC team) who will carry out the ethical monitoring in the scope of WP84.3?

Section 6.3.5 (page 58): it should be clarified what does the author refer to by saying that "real incidents may occur during the demonstration". Could you please clarify which type of incident you are considering, who is likely to be involved, whether do you have a risk mitigation strategy in place?

Section 6.3.6.3 (page 63): The last sentence should read: "The relevant data protection legislation will be respected, and the countries' competent authorities will be involved in this process".

Annexes: the Ethical Index Tool (EIT) should be included in the TAL. The "Informed consent form" may also be included as an Annex.

Links with other tasks and deliverables

The partner responsible for the Demo (INR) will continue working in strict collaboration with the partner responsible for the ethical monitoring (UCSC) in the scope of Task 84.3 Multi-C Demo Ethical Monitoring.
In addition, relevant Data Protection and Ethical Approvals will be collected in D11.4, which is led by BAES.

Final remarks

The most pressing ethical issues to be considered in this phase include:

- To provide clarification on the "real incidents" that may occur during the demonstration and related risk mitigation strategy;
- To clarify which Data Collection or Ethical Approvals have been sought from competent authorities and in which countries. Copies of these approvals will have to be submitted to the European Commission through D11.4;
- To clarify if the suggestions provided above are in line with the expectations for the "ethical monitoring" of this demonstration event (in particular, the request to identify the person who will be responsible to liaise with the Ethical Monitoring Officer).

Review summary

Ethical Issues

Does the document touch on any recognizable ethical issue? YES
If the answer is YES, you can continue

Research on Human Embryo/Foetus:

Question	NO	YES	Deliverable Page
Does the proposed research involve human Embryos?	X		
Does the proposed research involve human Foetal Tissues/Cells?	X		
Does the proposed research involve human Embryonic Stem Cells (hESCs)?	X		
Does the proposed research on human Embryonic Stem Cells involve cells in culture?	X		
Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?	X		

Research on Humans:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research	x		

involve children?			
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?	x		
Does the proposed research involve patients?	x		
Does the proposed research involve persons not able to give consent?	x		
Does the proposed research involve adult healthy volunteers?		x	
Does the proposed research involve Human genetic material?	x		
Does the proposed research involve Human biological samples?	x		
Does the proposed research involve Human data collection?		x	
Are the rights related to physical security and integrity[11] protected? N.A			
Are the rights related to the basic necessities of life[12] protected? N.A			
Does the proposed research respect the principle of non-discrimination?	N.A.		
Does a safeguard of victims' human rights exist?	N.A		
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?		x	
Are beneficence (doing good), non-maleficence (preventing or mitigating harm), personal dignity and respect of autonomy the most significant ethical values implied in your research?	N.A.		
For conducting research and manage the risk, do you need to involve other organizations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?		x	

Vulnerable Groups:

Question	NO	YES	Deliverable Page (if YES)

11 e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.

12 e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

Does the proposed research involve vulnerable groups?	x		
Are Human rights[13] be used as a framework to examine the effect of the Tools on vulnerable groups? x			
Is in this task discussed the concept of vulnerability?	x		
Does the proposed research reflect the fact that vulnerable groups have particular needs?	x		
Does the proposed research list the reasons that describe people as vulnerable?	x		
Are the groups of vulnerable people defined?	x		
Is there a categorization of groups by vulnerability?	x		
Are in this research the groups of vulnerable people whose personal integrity is compromised by the incident included?	x		

Informed Consent:

Question	NO	YES	Note (if No)
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?		x	
Will the volunteers receive written documentation of the same?		x	
Will the briefings and documentation be available in a language in which the subject is at home?		x	
Will briefings and documentation be free from jargon and readily accessible to non-specialists?		x	
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?		x	
Will volunteers be fully briefed as to their right to withdraw?		x	
Will volunteers be briefed as to the possible risks or benefits of participation?		x	
Will volunteers fully understand what they are required to do?		x	
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?		x	

13 Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

Where volunteers are introduced to the project through their employers (e.g. emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?		x	
Will volunteers have access to details of insurance coverage and medical provision relevant to the demonstration event?		x	
Will volunteers be given the names of responsible project members, including an assigned data controller?		x	
Will volunteers' understanding be checked in informal interviews?	x		
Will the informed consent and "opting-in" be documented?		x	

Privacy:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve processing of genetic information or personal data[14]? x			
Does the proposed research involve tracking the location or observation of people?		x	
Do you identify persons who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?		x	
Do you clarify to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?		x	
Do you follow or are you aware of any official national or international guidelines on protecting privacy?		x	
Do you follow written procedures for protecting privacy?		x	
Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?			See EDEN T11.4

14 e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

Is private information recorded?	x		
Is your organization insured against risks as a result of breach of privacy and safety?	x		

Data Collection:

Question	NO	YES	(Note if NO)
Are data gathered from individuals in accordance with relevant EU and national legal standards?		x	
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?		x	
Will data be stored securely?		x	

Research on Animals:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve research on animals?	x		
Are those animals transgenic small laboratory animals?	x		
Are those animals transgenic farm animals?	x		
Are those animals non-human primates?	x		
Are those animals cloned farm animals?	x		

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page (if YES)
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?	x		
Is any material used in the research[15]: a) Collected in any of the ICPC?	x		
b) Exported to any other country (including ICPC and EU Member States)?	x		

Dual Use:

Question	NO	YES	Page (if YES)
Does the proposed research have direct military use?	x		
Does the proposed	x		

15 e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

	research have the potential for terrorist abuse?			

Annex n°5: Ethics Review Document 3 (ERD03 – D61.1)

ETHICS REVIEW DOCUMENT ERD03

This form records the results of the Ethical Review of **EDEN D61.1 General Plan approved by Preliminary Review (ERD01)** in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Document under review	D61.1 General Plan approved by Preliminary Review
Author of the document	SGSP
Date of submission	July 25th 2014
Reviewer	Università Cattolica del Sacro Cuore (UCSC)
Date of review	May 26th 2014
Recommendations	This document is the General Plan approved by Preliminary Review – deliverable D61.1 of the *"End-user driven DEmo for cbrNe (EDEN)"*, a European 7th Framework EC funded project. This document presents the details of all organisational aspects on preparation and conducting process of series of 6 radiological and nuclear (RN) demonstrations scheduled in Work Package 60 (WP60) which are aimed to validate EDEN Project's RN Toolbox and its separate tools. It is also describing schemes of radiological and nuclear safety system of countries where demonstrations activities will take place (Poland, Italy, Ukraine) together with European Union and global systems.
Review summary	**CRITERION 1) Ethical Issues** Does the document touch on any recognizable ethical issue? If the answer is YES, you can continue **<u>Research on Human Embryo/Foetus:</u>**

Question	NO	YES	Deliverable Page
Does the proposed research involve human Embryos?	X		
Does the proposed research involve human Foetal Tissues/Cells?	X		
Does the proposed research involve human Embryonic Stem Cells (hESCs)?	X		
Does the proposed research on human Embryonic Stem Cells involve cells in culture?	X		
Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?	X		

Research on Humans:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve children?	X		
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?	X		
Does the proposed research involve patients?	X		
Does the proposed research involve persons not able to give consent?	X		
Does the proposed research involve adult healthy volunteers?	X		
Does the proposed research involve Human genetic material?	X		
Does the proposed research involve Human biological samples?	X		
Does the proposed research involve Human data collection?	X		
Are the rights related to physical security and integrity[16] protected? n.a			
Are the rights related to the basic necessities of life[17] protected? n.a			
Does the proposed	n.a		

[16] e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.

[17] e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

research prohibit a violation of the principle of non-discrimination?			
Does a safeguard of victims' human rights exist?	n.a		
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	n.a		
Are beneficence (doing good), non-maleficence (preventing or mitigating harm), personal dignity and respect of autonomy the most significant ethical values implied in your research?	n.a		
For conducting research and manage the risk, do you need to involve other organizations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?		X	Page 11

Vulnerable Groups:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve vulnerable groups?	X		
Are Human rights[18] be used as a			

[18] Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

framework to examine the effect of the Tools on vulnerable groups? n.a			
Is in this task discussed the concept of vulnerability?	n.a.		
Does the proposed research reflect the fact that vulnerable groups have particular needs?	n.a		
Does the proposed research list the reasons that describe people as vulnerable?	n.a		
Are the groups of vulnerable people defined?	n.a		
Is there a categorization of groups by vulnerability?	n.a		
Are in this research the groups of vulnerable people whose personal integrity is compromised by the incident included?	n.a		

Informed Consent:

Question	NO	YES	Note (if No)
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?	N.A.		
Will the volunteers receive written documentation of the same?	N.A.		
Will the briefings and documentation be available in a language in which the subject is at home?	N.A		
Will briefings and documentation be free from jargon and	N.A.		

readily accessible to non-specialists?				
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?	N.A			
Will volunteers be fully briefed as to their right to withdraw?	N.A			
Will volunteers be briefed as to the possible risks or benefits of participation?	N.A.			
Will volunteers fully understand what they are required to do?	N.A.			
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?	N.A			
Where volunteers are introduced to the project through their employers (e.g. emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?	N.A.			
Will volunteers have access to details of insurance coverage and medical provision relevant to the demonstration event?	N.A.			
Will volunteers be given the names of responsible project members, including	N.A.			

an assigned data controller?			
Will volunteers' understanding be checked in informal interviews?	N.A.		
Will the informed consent and "opting-in" be documented?	N.A.		

Privacy:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve processing of genetic information or personal data[19]? X			
Does the proposed research involve tracking the location or observation of people?	X		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	X		
Do you clarify to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	X		
Do you follow or are you aware of any official national or international guidelines on	X		

[19] e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

protecting privacy?			
Do you follow written procedures for protecting privacy?	X		
Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?	X		
Is private information recorded?	X		
Is your organization insured against risks as a result of breach of privacy and safety?	X		

Data Collection:

Question	NO	YES	(Note if NO)
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	N.A.		
Are data gathered from individuals in accordance with relevant EU and national legal standards?	N.A		
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?	N.A		
If data aren't gathered from individuals in accordance with relevant EU and	N.A		

national legal standards, later will be stored securely?			
Do you clarify to the people that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	N.A		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	N.A		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	N.A.		
Do you follow written procedures for protecting privacy?	N.A		
Is private information recorded?	N.A		

Research on Animals:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve research on animals?	X		
Are those animals transgenic small laboratory animals?	X		
Are those animals transgenic farm animals?	X		
Are those animals non-human primates?	X		
Are those animals	X		

cloned farm animals?			

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page (if YES)
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?	X		
Is any material used in the research[20]: a) Collected in any of the ICPC?	X		
b) Exported to any other country (including ICPC and EU Member States)?	X		

Dual Use:

Question	NO	YES	Page (if YES)
Does the proposed research have direct military use?	X		
Does the proposed research have the potential for terrorist abuse?	X		

[20] e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

Annex n°6: Ethics Review Document 5 (ERD05 – D23.4)

ETHICS REVIEW DOCUMENT (ERD05)

This form records the results of the Ethical Review of **EDEN D23.4 Constraints and scenarios for WP50 (ERD05)** in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

<table>
<tr><td>Document under review</td><td>D23.4 Constraints and scenarios for WP50</td></tr>
<tr><td>Author of the document</td><td>FORSVARETS FORSKNINGINSTITUTT (FFI)</td></tr>
<tr><td>Date of submission</td><td>June 30th 2014</td></tr>
<tr><td>Reviewer</td><td>Università Cattolica del Sacro Cuore (UCSC)</td></tr>
<tr><td>Date of review</td><td>July 15th 2014</td></tr>
<tr><td>Recommendations</td><td>This report presents scenarios and scenario constraints for the EDEN multi-C demonstrations. The five scenarios are C1: Petroleum refinery in Belgium, C2: Fertiliser facility in Romania, C3: Chemical site in France, C4: Sarin release in building ventilation system and C5: Bomb blast with suspected sulphur mustard. C1, C2 and C3 will be demonstrated in actual locations with operative end-users in collaboration with the site owners and national authorities. C4 and C5 will be conducted in one table-top demonstration involving different end-users including operative and medical personnel.
The document provides general descriptions of the Multi-C (Chemical) scenarios developed under WP23 (Task23.2). An overview of all five scenarios is given in the main body of this report, and further details are found on special scenario description templates included in an annex to this report.
The work is led by FFI with contributions from INR, MDA, FhG EMI and SES.
The scope of the document is to select and provide general descriptions of the Multi-C scenarios suitable for application in WP50. Further details necessary for the actual running of each scenario at a given time and location must be provided in WP50.

As far as the ethical monitoring is concerned, no serious ethical issue has been detected in this report.</td></tr>
<tr><td>Review summary</td><td>CRITERION 1) Ethical Issues

Does the document touch on any recognizable ethical issue?
If the answer is YES, you can continue

<u>Research on Human Embryo/Foetus:</u>
<table>
<tr><th>Question</th><th>NO</th><th>YES</th><th>Deliverable Page</th></tr>
<tr><td>Does the proposed research involve human Embryos?</td><td>X</td><td></td><td></td></tr>
<tr><td>Does the proposed research involve human Foetal Tissues/Cells?</td><td>X</td><td></td><td></td></tr>
<tr><td>Does the proposed research involve human Embryonic Stem Cells (hESCs)?</td><td>X</td><td></td><td></td></tr>
<tr><td>Does the proposed research on human Embryonic Stem Cells involve cells in culture?</td><td>X</td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?	X		

Research on Humans:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve children?	X		
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?	X		
Does the proposed research involve patients?	X		
Does the proposed research involve persons not able to give consent?	X		
Does the proposed research involve adult healthy volunteers?	X		
Does the proposed research involve Human genetic material?	X		
Does the proposed research involve Human biological samples?	X		
Does the proposed research involve Human data collection?	X		
Are the rights related to physical security and integrity[21] protected? n.a.			
Are the rights related to the basic necessities of life[22] protected? n.a.			
Does the proposed research prohibit a violation of the principle of non-discrimination?	n.a.		
Does a safeguard of victims' human rights exist?	n.a.		
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?		X	
Are beneficence (doing good), non-maleficence (preventing or mitigating harm), personal dignity and respect of autonomy the	n.a.		

[21] e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.

[22] e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

most significant ethical values implied in your research?			
For conducting research and manage the risk, do you need to involve other organizations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?	X		

Vulnerable Groups:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve vulnerable groups?	X		
Are Human rights[23] be used as a framework to examine the effect of the Tools on vulnerable groups? X			
Is in this task discussed the concept of vulnerability?		X	
Does the proposed research reflect the fact that vulnerable groups have particular needs?	X		
Does the proposed research list the reasons that describe people as vulnerable?	X		
Are the groups of vulnerable people defined?	X		
Is there a categorization of groups by vulnerability?	X		
Are in this research the groups of vulnerable people whose personal integrity is compromised by the incident included?	X		

Informed Consent:

Question	NO	YES	Note (if No)
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?	N.A.		
Will the volunteers receive written documentation of the same?	N.A.		
Will the briefings and documentation be available in a language in which the subject is at home?	N.A		
Will briefings and	N.A.		

[23] Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

documentation be free from jargon and readily accessible to non-specialists?			
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?	N.A		
Will volunteers be fully briefed as to their right to withdraw?	N.A		
Will volunteers be briefed as to the possible risks or benefits of participation?	N.A.		
Will volunteers fully understand what they are required to do?	N.A.		
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?	N.A		
Where volunteers are introduced to the project through their employers (e.g. emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?	N.A.		
Will volunteers have access to details of insurance coverage and medical provision relevant to the demonstration event?	N.A.		
Will volunteers be given the names of responsible project members, including an assigned data controller?	N.A.		
Will volunteers' understanding be checked in informal interviews?	N.A.		
Will the informed consent and "opting-in" be documented?	N.A.		

Privacy:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve processing of genetic information or personal data[24]? X			
Does the proposed research involve tracking the location or observation of people?	X		
Do you identify persons and	X		

[24] e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?			
Do you clarify to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	X		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	X		
Do you follow written procedures for protecting privacy?	X		
Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?	X		
Is private information recorded?	X		
Is your organization insured against risks as a result of breach of privacy and safety?	X		

Data Collection:

Question	NO	YES	(Note if NO)
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	N.A.		
Are data gathered from individuals in accordance with relevant EU and national legal standards?	N.A		
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?	N.A		
If data aren't gathered from individuals in accordance with relevant EU and national legal standards, later will be stored securely?	N.A		
Do you clarify to the people that all data collected in the activities they are	N.A		

participating in will be kept entirely confidential and that their anonymity will be protected in full?			
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	N.A		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	N.A.		
Do you follow written procedures for protecting privacy?	N.A		
Is private information recorded?	N.A		

Research on Animals:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve research on animals?	X		
Are those animals transgenic small laboratory animals?	X		
Are those animals transgenic farm animals?	X		
Are those animals non-human primates?	X		
Are those animals cloned farm animals?	X		

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page (if YES)
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?	X		
Is any material used in the research[25]: a) Collected in any of the ICPC?	X		
b) Exported to any other country (including ICPC and EU Member States)?	X		

Dual Use:

Question	NO	YES	Page (if YES)

[25] e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

	Does the proposed research have direct military use?	X		
	Does the proposed research have the potential for terrorist abuse?	X		

Annex n°7: Ethics Review Document 6 (ERD06 – D23.5)

ETHICS REVIEW DOCUMENT ERD06

This form records the results of the Ethical Review of **D23.5 Constraints and scenarios for WP60** in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Document under review	**D23.5 Constraints and scenarios for WP60**
Author of the document	FFI
Date of submission	July 25th 2014
Reviewer	Università Cattolica del Sacro Cuore (UCSC)
Date of review	July 29th 2014
Recommendations	The work is led by FFI with contributions from SGSP, FHG-INT, FHG-EMI, ENEA, HZS, SES and SRC This document provides general descriptions of all radiological and nuclear (RN) scenarios developed under WP23. The objective of EDEN WP23 *Scenario development* is to develop detailed scenarios in order, for instance, to demonstrate improved capability to prevent, manage and recover from a large RN crisis following a nuclear power plant sabotage including population evacuation, etc.; to manage a dirty bomb explosion in a public area, generating panic; and to locate a hidden radioactive source in a wide urban area. The scenarios developed are: RN1: Dirty bomb field exercise in Poland; Two versions of this scenario have been developed, a "large-scale" explosion and a "small-scale" explosion, referred to as scenarios RN1a and RN1b, respectively. RN2: Handling of major nuclear facility accident. This scenario is intended for a tabletop exercise. The activity will be run as an exercise in international crisis management in the event of a nuclear facility failure, focusing on effective information sharing and coordination of activities between players on regional and national level.. RN3: Terrorist attack on virtual nuclear facility. The activity will demonstrate the possibility of using new tools in the preparedness phase.. RN4.1: Smuggling of radioactive materials. In this scenario, terrorists steal radioactive material and make an attempt to smuggle this into a neighbouring country, with the aim of using it in a dirty bomb or criminal activities like blackmailing. RN4.2: Dirty bomb threat analysis. The aim of the exercise is to test the operation of techniques intended to speed up the response time for assessing possible presence of hazardous materials in a container without exposing the operators to any threats. RN4.3: Faulty reactor fuel rod discovered by optical technique. The scenario gives a background for the demonstration of a newly developed system that uses innovative optical techniques to monitor the reactor core and prevent operational faults in a nuclear reactor facility. RN5.1: Operational fault in a nuclear reactor. This is a field exercise inside the nuclear facility at ENEA Casaccia. The scenario is about the simulation of a severe radioactive release caused by an accident occurring in the TRIGA nuclear reactor. It is assumed that an operational fault is the cause of the release of radiological material. RN5.2: Rescue and decontamination effort. This is a field exercise which

	will take place in Pripyat near the Chernobyl Nuclear Power Plant (NPP) in Ukraine. This is a ghost town in the exclusion zone. It had 47 000 inhabitants in the past, and it is currently a safe area for participants. These scenarios and subsequent gaps, needs, requirements and tools analysis are a basis for building the demonstrations. As far as the ethical monitoring is concerned, no major ethical issue has been detected in this report

Review summary

CRITERION 1) Ethical Issues

Does the document touch on any recognizable ethical issue?
If the answer is YES, you can continue

Research on Human Embryo/Foetus:

Question	NO	YES	Deliverable Page
Does the proposed research involve human Embryos?	X		
Does the proposed research involve human Foetal Tissues/Cells?	X		
Does the proposed research involve human Embryonic Stem Cells (hESCs)?	X		
Does the proposed research on human Embryonic Stem Cells involve cells in culture?	X		
Does the proposed research on human Embryonic Stem Cells involve the derivation of cells from Embryos?	X		

Research on Humans:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve children?	X		
Does the proposed research involve volunteers unable to give genuinely informed consent (e.g. minors)?	X		
Does the proposed research involve patients?	X		
Does the proposed research involve persons not able to give consent?	X		
Does the proposed research involve adult healthy volunteers?		X	
Does the proposed research involve Human genetic material?	X		
Does the proposed research involve Human biological samples?	X		
Does the proposed research involve Human data collection?	X		
Are the rights related to physical security and integrity[26] protected? n.a.			
Are the rights related to the basic necessities of life[27]			

[26] e.g. protection of the right to life and the right to be free from assault, rape, arbitrary detention, kidnapping, and threats concerning the above.

[27] e.g. the rights to food, drinking water, shelter, adequate clothing, adequate health services, and sanitation.

protected? n.a.			
Does the proposed research prohibit a violation of the principle of non-discrimination?	n.a.		
Does a safeguard of victims' human rights exist?	n.a.		
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?		X	
Are beneficence (doing good), non-maleficence (preventing or mitigating harm), personal dignity and respect of autonomy the most significant ethical values implied in your research?	n.a.		
For conducting research and manage the risk, do you need to involve other organizations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?	X		

Vulnerable Groups:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve vulnerable groups?	X		
Are Human rights[28] be used as a framework to examine the effect of the Tools on vulnerable groups? X		See Recommendations section above	
Is in this task discussed the concept of vulnerability?	X		
Does the proposed research reflect the fact that vulnerable groups have particular needs?	X		
Does the proposed research list the reasons that describe people as vulnerable?	X		

[28] Specially European Convention on Human Rights, the Universal Declaration of Human Rights, Convention on the Rights of Persons with Disabilities and its Optional Protocol, Universal Declaration on Bioethics and Human Rights

Are the groups of vulnerable people defined?	X		
Is there a categorization of groups by vulnerability?	X		
Are in this research the groups of vulnerable people whose personal integrity is compromised by the incident included?	X		

Informed Consent:

Question	NO	YES	Note (if No)
Will the volunteers be verbally briefed on the project, its nature and scope, and aims?	N.A.		
Will the volunteers receive written documentation of the same?	N.A.		
Will the briefings and documentation be available in a language in which the subject is at home?	N.A		
Will briefings and documentation be free from jargon and readily accessible to non-specialists?	N.A.		
Will volunteers have access – before, during and after the events – to demonstration organizers who can advise them on any issues, questions, doubts, comments they may have?	N.A		
Will volunteers be fully briefed as to their right to withdraw?	N.A		
Will volunteers be briefed as to the possible risks or benefits of participation?	N.A.		
Will volunteers fully understand what they are required to do?	N.A.		
Will volunteers understand that they will not be placed in any situation in which there is a likelihood of physical, mental or emotional harm?	N.A		
Where volunteers are introduced to the project through their employers (e.g. emergency service personnel), will it be ensured that they are under no undue explicit or implicit pressure to take part?	N.A.		
Will volunteers have access	N.A.		

to details of insurance coverage and medical provision relevant to the demonstration event?			
Will volunteers be given the names of responsible project members, including an assigned data controller?	N.A.		
Will volunteers' understanding be checked in informal interviews?	N.A.		
Will the informed consent and "opting-in" be documented?	N.A.		

Privacy:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve processing of genetic information or personal data[29]? X			
Does the proposed research involve tracking the location or observation of people?	X		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	X		
Do you clarify to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?		X	
Do you follow or are you aware of any official national or international guidelines on protecting privacy?		X	
Do you follow written procedures for protecting privacy?	X		
Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?	X		
Is private information recorded?	X		
Is your organization insured	X		

[29] e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.

against risks as a result of breach of privacy and safety?			

Data Collection:

Question	NO	YES	(Note if NO)
Is your research conducted in order to systematically collect and analyze data for drawing conclusions aimed at improving the care of potential beneficiaries in the future?	X		
Are data gathered from individuals in accordance with relevant EU and national legal standards?	N.A		
Are personal data gathered only for specified, legitimate purposes and not used except for those purposes?	N.A		
If data aren't gathered from individuals in accordance with relevant EU and national legal standards, later will be stored securely?	N.A		
Do you clarify to the people that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?	N.A		
Do you identify persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, both, paper-based and electronically?	N.A		
Do you follow or are you aware of any official national or international guidelines on protecting privacy?	N.A.		
Do you follow written procedures for protecting privacy?	N.A		
Is private information recorded?	N.A		

Research on Animals:

Question	NO	YES	Deliverable Page (if YES)
Does the proposed research involve research on animals?	X		
Are those animals	X		

transgenic small laboratory animals?			
Are those animals transgenic farm animals?	X		
Are those animals non-human primates?	X		
Are those animals cloned farm animals?	X		

Research involving "International Cooperation Partner Country" (ICPC):

Question	NO	YES	Deliverable Page (if YES)
Is the proposed research (or parts of it) going to take place in the one or more of the ICPC?	X		
Is any material used in the research[30]: a) Collected in any of the ICPC?	X		
b) Exported to any other country (including ICPC and EU Member States)?	X		

Dual Use:

Question	NO	YES	Page (if YES)
Does the proposed research have direct military use?	X		
Does the proposed research have the potential for terrorist abuse?	X		

[30] e.g. personal data, animal and/or human tissues samples, genetic material, live animal, etc.

Annex N°8: Ethical Review of EDEN T83.1 on Public Perception

ETHICS REVIEW DOCUMENT FOR T83.1

This form records the results of the Ethical Review of EDEN T83.1 in the scope of T84.5, and issues a set of recommendations in order to align the deliverable and related activities to the highest ethical standards at the EU level.

Specific comments may be added to deliverables using the "comments", "tracked change" (etc.) functions.

Documents under review	EDEN T83.1 Questionnaire EDEN T83.1 Interview Guide EDEN T83.1 Information Sheet EDEN T83.1 Interview Consent Form
Author of the document	Dave Usher
Date of submission	30th May 2014
Reviewer	Emma Traisci
Date of review	9th June 2014
Recommendations	**Comments on "Information sheet" and "Consent form"** 3 The reassurance of complete anonymity of the questionnaire and the request to sign the consent form may be in contradiction. Considering that, in order to carry out the research, you should seek the participants' consent, you might make the consent form and the completed questionnaires only *indirectly linkable* (through, for instance, a "number" as the same identifier of both documents) to guarantee the respondent's anonimity. We suggest that you identify a "data controller" within your team, who will be responsible for the collection of personal data, and will be able to link the consent form with the related questionnaire, only if need be (e.g., an audit). **Comments on the Questionnaire** 4 We suggest to include an additional question on the respondent's opinion on the impact of surveillance technologies on human rights (e.g., privacy, data protection, fundamental freedoms, etc...). This may help to evaluate not only the perceived efficacy of the technologies, but also the perceived effect on human rights protection. 5 We suggest to include a question about the kind of expert you are interviewing (academic expert, policy maker, first responder, etc)