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Deliverable D8.3

Materials and briefing for PROACTIVE exercises

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Project details

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Consortium – List of partners

Partner no.	Short name	Name	Country
1	UIC	UNION INTERNATIONALE DES CHEMINS DE FER (COORDINATOR)	France
2	CBRNE	CBRNE LTD	UK
3	PPI	POPULATION PROTECTION INSTITUTE (MINISTRY OF THE INTERIOR OF THE CZECH REPUBLIC)	Czech Republic
4	DB	DEUTSCHE BAHN AG	Germany
6	UMU	UMEA UNIVERSITET	Sweden
7	DHPOL	DEUTSCHE HOCHSCHULE DER POLIZEI	Germany
8	RINISOFT	RINISOFT LTD	Bulgaria
9	WMP	WEST MIDLANDS POLICE AND CRIME COMMISSIONER	UK
10	ETICAS	ETICAS RESEARCH AND CONSULTING SL	Spain
11	SESU	STATE EMERGENCY SERVICE OF UKRAINE	Ukraine
12	PHE	DEPARTMENT OF HEALTH	UK
13	SPL	STATE POLICE OF LATVIA	Latvia
14	AGS	AN GARDA SÍOCHÁNA – NATIONAL POLICE FORCE IRELAND	Ireland
15	FFI	FORSVARETS FORSKNINGSINSTITUTT	Norway
16	NPH	KOMENDA GŁÓWNA POLICJI	Poland

Executive summary

This document has been written for practitioners and researchers taking part in the PROACTIVE & eNOTICE Joint Activity field exercises, to provide them with a good understanding of the main legal and ethical norms by which they should abide. The document defines the legal and ethical framework for the PROACTIVE field exercises which, together with D7.4, underlines the “in vitro” aspects for PROACTIVE activities.

It aims at ensuring that basic legal and ethical norms applicable in the host countries are considered when designing and conducting the exercises. While its main audience is the PROACTIVE consortium, the document will also be of great help for eNOTICE and the training center hosts of the exercise. PROACTIVE’s Grant Agreement anticipated a total of three exercises, taking place in France, Germany and Poland. In the context of an updated eNOTICE event planning and the COVID-19 pandemic, the dates and locations of the joint exercises has had to be rescheduled. At the moment, the field exercise that was expected to be carried out in France will take place in Italy instead. The exercise due to take place in Poland is now expected to be held in Belgium. The original descriptions of the field exercises to be carried out in Rieti (Italy), Dortmund (Germany) and Ranst (Belgium) are described in Tasks 6.3, 6.4 and 6.5.

Because of the ongoing nature of COVID-19 pandemic, the timeline of the exercises is under review.

Regarding the nature of the collaboration between PROACTIVE and eNOTICE, both PROACTIVE’s Grant Agreement and various communications among members of both consortia indicate that there is good reason to assume that the exercises conducted in Italy, Germany and Belgium will be primarily co-designed and supervised by the eNOTICE consortium and the eNOTICE partner hosting the exercise. However, the involvement of external members of the public including representatives of vulnerable groups will take place for the purposes of achieving PROACTIVE’s research objectives and, thus, will be managed primarily by the PROACTIVE consortium in collaboration with eNOTICE.

As part of PROACTIVE Task T8.3, the present document focuses on providing the general framework on the ethical management of the participants focusing on the recommendations regarding privacy and data protection rights, Informed Consent and the management of volunteers in an ethical manner. Health and safety considerations are also included, which is an issue of the utmost importance when conducting research that could entail a certain degree of risk for the participants involved, including vulnerable people.

The Deliverable is issued as a Guideline for use by Practitioners carrying out joint exercises. As the planning process for the field exercises is advancing, for each field exercise the guidelines presented in this document will be adapted to specific protocols, procedures and documents and will become part of the Exercise Action Plan, as underlined in the IIMARCH methodology developed in D6.1 *The PROACTIVE Methodology for field exercises*.

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1. INTRODUCTION

PROACTIVE is an EU funded project within the H2020 framework, addressing topic SU-FCT01 2018 2019 2020: Human factors, and social, societal, and organisational aspects to solve issues in fighting against crime and terrorism. It began on 1st of May 2019 and will finish on 30th of April 2022.

PROACTIVE aims to increase practitioner effectiveness in managing large and diverse groups of people in a chemical, biological, radiological, nuclear and explosive (CBRNe) environment. The main goal is to enhance preparedness against and response to a CBRNe incident through a better harmonisation of procedures between various categories of practitioners, and a better articulation with the needs of vulnerable citizen groups.

PROACTIVE will result in toolkits for CBRNe Practitioners and for civil society organisations. The toolkit for Practitioners will include a web collaborative platform with database scenarios for communication and exchange of best practices among Law Enforcement Agencies (LEAs) and Policy Makers, as well as an innovative response tool in the form of a mobile app. The toolkit for the civil society will include a mobile App adapted to various vulnerable citizen categories and pre incident public information material.

The collaboration between the PROACTIVE and the eNOTICE consortia is described in PROACTIVE's Grant Agreement (number 832981), which includes a preliminary letter of cooperation signed by Olga Vybornova on behalf of eNOTICE during the PROACTIVE proposal phase. A more detailed letter of cooperation was signed in December 2019 by the authorised representatives of the two projects. This cooperation was justified based on the logistical and economic synergies.

PROACTIVE Task T6.1 is responsible for the planning and administration of the three field exercises coordinated in conjunction with the eNOTICE consortium. These joint exercises will include volunteers recruited by PROACTIVE and will be aimed at testing the acceptability and usability of specific tools, procedures and technology with a view to improving the interaction between Practitioners, policy makers and members of the public including vulnerable people.

A key issue tackled in this briefing document is the implication that "vulnerability" has on other matters related to research during the three field exercises, including recruitment practices, the health and the safety, as well as privacy and data protection rights.

Regarding the nature of the collaboration between PROACTIVE and eNOTICE, in line with the PROACTIVE-eNOTICE cooperation letter and various communications between both consortia, there is good reason to assume the exercises conducted in Italy, Germany and Belgium will be primarily designed and supervised by the eNOTICE consortium in tandem with the host training center. However, the involvement of members of the general public including vulnerable groups as human participants will take place for the purpose of achieving PROACTIVE's research objectives and, thus, will be managed primarily by the PROACTIVE consortium in collaboration with eNOTICE.

PROACTIVE's Grant Agreement anticipated a total of three exercises, taking place in France, Germany and Poland (Tasks 6.3, 6.4 and 6.5). At the moment, the field exercises are planned to be carried out in in Rieti (Italy), Dortmund (Germany) and Ranst (Belgium). Because of the ongoing

nature of COVID-19 pandemic, the timeline of the exercises is under review. Based on the latest discussions between eNOTICE and PROACTIVE in March 2021, the current expected timeline of field exercises is:

- Dortmund (Germany) – April 2022
- Rieti (Italy) – October 2022
- Ranst (Belgium) – May 2023

In view of the task descriptions and discussions between ETICAS and CBRNE, it seems reasonable to assume logistics of the exercises and specific conditions to which research participants will be exposed are only partially determined at this point. Nevertheless, vulnerable people will be involved in the exercises, particularly minors, the elderly and disabled people. Project PROACTIVE defines 'vulnerable groups' as members of the public with needs that differ from those of the average population when being affected by a CBRNe incident. This may include children, pregnant women, persons with physical or psychological disabilities, chronic medical disorders, acute health conditions or addictions, older persons with functional limitations and health restrictions, institutionalized individuals as well as their caregivers and companions. Vulnerable citizens also include persons with limited proficiency of the respective national languages or with restrictions regarding use of transportation, as well as individuals who are not prepared to undress for decontamination.

The terminology is useful to clarify the distinction between research ethics and subject matter ethics in the context of PROACTIVE: *research ethics*, as "in vitro" represents the moral principles and the procedures that govern how researchers carry out studies and simulations with people, for research purposes; *subject matter ethics,* as "in vivo" represents the moral principles and the procedures that govern the real life circumstances of practitioners dealing with citizens.

Thus, this document defines the legal and ethical framework for the PROACTIVE field exercises which, together with D7.4, underlines the "in vitro" aspects for PROACTIVE activities, and focuses on providing the general framework on the ethical management of the exercise participants. It focuses on the recommendations regarding privacy and data protection rights, as well as Informed Consent and the safety of research participants. These are issues of the utmost importance when conducting research which entails a certain degree of risk for the participants, including vulnerable people.

This deliverable is issued as a Guideline for use by Practitioners carrying out joint exercises. As the planning process for the field exercises is advancing, for each field exercise the guidelines presented in this document will be adapted to specific protocols, procedures and documents and will become part of the Exercise Action Plan. as underlined in the IIMARCH methodology developed in D6.1 *The PROACTIVE Methodology for field exercises*. The IIMARCH framework allows PROACTIVE field exercises' operational planners to ensure that all aspects of planning are incorporated in a comprehensive and logical manner. The structure of each PROACTIVE Exercise Action Plan will follow this framework.

It is important to mentioned in this context that the key output from application of the IMMARCH Methodology will be a series of completed Templates, specific to each exercise, that will enable the Project to ensure that the three field exercises will deliver the results and data it needs, in a consistent

manner, in adherence with the Project's Ethical standards, among others. The specific content of these templates will always follow the framework and will be completed in detail once the scenario content, location and parameters are agreed.

2. PURPOSE AND CONTENT OF THIS DOCUMENT

Medical articles for general audiences often use the terms "in vitro" and "in vivo" to describe medical research and studies. *In vitro* is Latin for "in glass": it describes medical procedures, tests and experiments that researchers perform in a controlled environment, such as a test tube or petri dish. *In vivo* is Latin for "with the living": it refers to tests, experiments and procedures that researchers perform in or on a whole living organism, such as a person, laboratory animal or plant (Eldridge, 2019).

As stated in the introduction, the terminology is useful to clarify the distinction between research ethics and subject matter ethics in the context of PROACTIVE: *research ethics*, as "in vitro" represents the moral principles and the procedures that govern how researchers carry out studies and simulations with people, for research purposes; *subject matter ethics,* as "in vivo" represents the moral principles and the procedures that govern the real life circumstances of practitioners dealing with citizens.

The deliverable 8.1 *Legal and Ethical State of the Art on CBRNe preparedness and response* supports the consortium partners to identify the subject matter ethics, the "in vivo" ethics requirements regarding CBRNe response at the EU level, focusing on the emergency assistance of vulnerable groups. In this deliverable we are defining the legal and ethical framework for the PROACTIVE field exercises which, together with D7.4, underlines the "in vitro" aspects for PROACTIVE activities.

D8.3 aims at providing practitioners and researchers taking part in the PROACTIVE & eNOTICE Joint Activity field exercises with a good understanding of the main legal and ethical norms by which they should abide in this context. Evidently, this document does not intend to replace or be a comprehensive summary of the legal and ethical guidelines (see deliverable D8.1 *Legal and ethical state-of-the-art on CBRNe preparedness and response* for a more detailed review). Instead, it aims at ensuring that basic legal and ethical practices applicable in the host countries are considered when designing and conducting the exercises. While its main audience is the PROACTIVE consortium, the document will also be of great help for eNOTICE and the training center hosts of the exercise.

As part of task T8.3, this document will ensure total compliance of PROACTIVE with the EU regulatory framework, as well as with ethical principles and establishes specific measures to guarantee respect for the fundamental rights embedded in the regulatory framework of the EU during the development of the project fieldwork.

In terms of the issues discussed in this document, the most relevant are the following:

- **Regulatory framework (Section 3)** addresses the legal framework relevant for the field exercises; PROACTIVE will ensure research activities are carried out in a way that is legally compliant and ethically appropriate. In particular, Informed Consent and data processing activities must abide by the General Data Protection Regulation and other relevant pieces of legislation on this matter. In addition to that, the consortium's approach on research ethics will be informed by documents published by the European Commission, as well as by international treaties and conventions on human rights.

- **Management of volunteers in an ethical manner (Section 4)** focuses on the procedures related to the recruitment of volunteers (including vulnerable citizens), Informed Consent, briefings, welfare and risk assessment for the benefit of and during the field exercises.

- **Insurance Cover (Section 5)** examines the need for insurance.

- **Health and Safety measures (Section 6)**; as part of the specific Exercise Action Plan, the PROACTIVE consortium will assess the health and safety risks to which participants will be exposed during the exercises and will implement mitigation measures to ensure their physical and psychological integrity is preserved at all times. The assessment will give special emphasis to the needs of the vulnerable participants. Volunteers will be informed about the risks that come with participating in the research activities which forms part of their right to information and constitutes a prerequisite for Informed Consent. These observations will form the basis for the development of safety instructions and practical guidelines that will be commonly agreed by PROACTIVE and e-NOTICE.

- **Ethics supervision during the field exercises (Section 7)** will present the procedures supporting the ethical oversight of the field exercises and set up the role and involvement of the Ethics and Data Protection Supervisor and of the members of the PROACTIVE Ethics Advisory Board.

3. REGULATORY FRAMEWORK

The field and practise of emergency management are dominated by topics such as risk assessment, the disaster or emergency management cycle, logistics, planning, legislation, policy and standards; and focuses on the optimum ways to achieve goals such as reducing harmful economic impacts and loss of life (Etkin & Timmerman, 2013). Issues related to ethics, values and human relations are rare in most mainstream EM literature, though they are common in other related fields, as disaster or public health related management (Zack 2009).

Deliverable D8.1 *Legal and Ethical State-of-the-Art on CBRNe preparedness and response* (section 3) establishes the ethical framework for PROACTIVE project ('in vivo' aspects: moral principles and the procedures that govern the real life circumstances of practitioners dealing with citizens) and supports the consortium partners to identify the ethics requirements in regard of CBRN response at the EU level, focusing on the emergency assistance of vulnerable groups. In establishing the PROACTIVE ethical framework we have adopted the human rights approach to disaster management. We list here in brief the main ethical values and the main ethical principles & standards of PROACTIVE ethical framework.

Ethical values (Rice & all, 2017, p.119): equality, transparency, accountability and empowerment. Specifically, *equality* refers to ensuring those in need receive the resources they are entitled to, while *transparency* ensures those affected by the disaster have full access to information in order to make informed decisions. *Accountability* refers to holding those with power and ability to distribute those resources responsible for doing so. While distributing resources and rebuilding post disaster, it is essential that those affected are *empowered* through participation in the recovery in order to ensure sustainable effects.

Ethical principles and standards (EUR-OPA, Resolution 2011-1, pp 27-31):

- **Humanitarian assistance:** all persons receive immediate assistance, including the benefit of basic health services. Humanitarian assistance is provided fairly, impartially and without discrimination, showing due regard for the vulnerability of victims and for individuals' and groups' specific needs.

- **Information and communication during disasters:** all persons, local and regional authorities and non-governmental organisations affected by disasters are informed of and are entitled to participate in making decisions in response to disasters. They receive, in their own language, easily understandable information about the nature and extent of the disaster, the emergency measures planned in response to it, the times and places at which food and drink will be distributed, the location of emergency medical facilities, temporary housing arrangements and the arrangements for and destination of any population movements that are planned.

- **Compulsory evacuation of population:** compulsory evacuation can only take place if a clear explanation has been given of the potential risks involved in the case of non-evacuation. Persons who refuse to evacuate do so at their own risk and should not endanger the lives of rescue workers through their conduct

- **Respect of dignity:** the dignity of all persons who are victims is respected, particularly concerning his/her security, physical safety, access to food and clean water, hygiene, temporary housing, clothing and if necessary essential emergency medical and psychological care

- **Respect of persons:** personal rights are respected, particularly the right to one's own image and the right to privacy, so that the presence of the media does not result in abuses

- **Emergency assistance for the most vulnerable persons:** allowing for local circumstances and without prejudice to the priority assistance to be given to all who have a chance of survival, priority for humanitarian assistance, first aid and emergency evacuations go in priority to the most vulnerable people, such as pregnant women, children, people with disabilities, elderly people, the ill and the wounded. States train and provide special equipment to members of the emergency services and doctors and nurses so that they are able to search for and provide first aid to the most fragile persons.

- **The importance of rescue workers:** Irrespective of their nationality, theirs status or their function and regardless of the seriousness and nature of the disaster, both civilian and military rescue workers, including any private security forces, behave with dignity, keep their

anxiety of fear under control, keep calm and ensure that they never infringe the fundamental rights of the people they are rescuing.

  - States, international organisations and all institutions connected with humanitarian assistance in response to disasters take every possible measure to guarantee to rescue workers the necessary conditions for them to carry out their work properly, including the conditions needed to protect their dignity, safety, and physical and psychological integrity.

  - States, regional and local authorities and rescue training establishments provide special training to rescue workers covering human rights and ethical principles in times of disaster and the special arrangements for dealing with persons with disabilities and the most vulnerable persons.

- **Measures to safeguard and rehabilitate the environment:** In view of the importance of the environment to human survival, practical measures are taken to ensure the quickest possible safeguarding and rehabilitation of environmental assets and the re-establishment of environmental quality.

- **Measures to safeguards and restore social ties:** considering the importance of social ties to human survival, practical measures are taken to ensure that social ties are restored as quickly as possible, in particular by foreseeing meeting places, place of worship and places for leisure activities.

As we have mentioned in the introduction, the purpose of D8.3 is to define the legal and ethical framework for the PROACTIVE field exercises which, together with D7.4, underlines the “in vitro” aspects for PROACTIVE activities. In this respect, this section addresses main legal aspects framing PROACTIVE research activities during the field exercises, based on the high level ‘in vivo’ ethics requirements identified in D8.1.

There are three major areas for which regulations are relevant:

- Human rights, in respect to human participants, including vulnerable citizens;

- Privacy and data protection in respect to inform consent and personal data processing; and

- Research ethics in respect to the ethical and legal governance framework for PROACTIVE research and activities, including field exercises.

3.1. Human rights

One of the fundamental principles of ethical research involving human beings is the maintenance of their human rights. This is particularly relevant to PROACTIVE as it intends to involve volunteers, including those vulnerable, in field exercises to assess their particular needs and, thus, improve the practitioners’ response.

The human rights to privacy, protection of personal data, non-discrimination and integrity have been identified as the most relevant ones for this project. These four human rights are examined in Section 2.1 (Human rights) of D8.1 *Legal and Ethical State of the Art on CBRNe preparedness and*

response. Definitions and requirements to be followed in relation to the rights to integrity (Art 3 CFR), privacy (Article 7 CFR), and human rights regarding rights of the child, the elderly, people with disabilities and religious minorities are considered based on applicable international Conventions and the CFR articles.

3.2. Privacy and data protection

The relevant privacy and data protection requirements for project PROACTIVE research activities are presented in D7.4 *Data Management Plan and Research Ethics,* considering data protection requirements detailed in D8.1. Also, D10.5 *Protection of Personal Data Requirement no 5* describes in details the technical and organisational measures, including the pseudonymisation and anonymisation techniques that will be implemented in PROACTIVE in order to protect the privacy and data protection rights of data subjects and research participants.

In respect of the field exercises carried out in conjunction with eNOTICE, among the aspects that privacy and data regulations cover, the following will be the most relevant:

- Roles, responsibilities and governance;
- Informed Consent;
- Data Management.

3.2.1. Roles and responsibilities for PROACTIVE and eNOTICE

This Section highlights the clear roles allocated to the two projects.

In observance of the principle of accountability, roles and responsibilities regarding data processing must be assigned. The following articles define the concepts of controller, processor and joint controllers[1]:

Article 4(7) GDPR

*'**controller**' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;*

Article 4(8) GDPR

*'**processor**' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;*

[1] See https://gdpr-info.eu/

Article 26 GDPR

*1. Where two or more controllers jointly determine the purposes and means of processing, they shall be **joint controllers**. They shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the exercise of the rights of the data subject and their respective duties to provide the information referred to in Articles 13 and 14, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the controllers are determined by Union or Member State law to which the controllers are subject. The arrangement may designate a contact point for data subjects.*

2. The arrangement referred to in paragraph 1 shall duly reflect the respective roles and relationships of the joint controllers vis-à-vis the data subjects. The essence of the arrangement shall be made available to the data subject.

3. Irrespective of the terms of the arrangement referred to in paragraph 1, the data subject may exercise his or her rights under this Regulation in respect of and against each of the controllers.

By joint agreement, project PROACTIVE and project eNOTICE, decided project PROACTIVE will be the controller as it determines the purposes and means of the processing since it recruits participants and handles their personal data.

Anonymised personal data could be shared with eNOTICE for research purposes if required. The process of anonymisation should be mentioned in the consent form as Article 13 of the GDPR requires it. As a matter of course, all data should be pseudonymised or anonymised to the highest possible degree before being shared in order to preserve data subject's privacy as much as possible while allowing for research to be carried out.

3.2.2. Informed Consent

Participants **need to give their free and Informed Consent according to the best ethical practices and in compliance with the requirements of the GDPR.** To comply with article 13 of GDPR, consent forms including all the necessary information regarding the processing of their data will be produced. Participants also need to give Informed Consent regarding their expectations of the exercise e.g. consent to take part, consent to undergo filming, etc. Informed Consent will be available in local languages.

According to article 4(11) of GDPR, "*'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her*". Thus, consent should be given freely, in a specific manner, clearly and after the data subject was informed of the processing activities. Therefore, the specific ways in which consent will be gathered from participants will need to abide by these principles and others already considered in previous papers and guidelines.

The GDPR defines personal data broadly in order to increase protection of the individuals. Hence, personal data are "*any information relating to an identified or identifiable natural person*", i.e. the

data subject, "*who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*"[2]. Furthermore, "*data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, [as well as] genetic data, biometric data […], data concerning health or data concerning a natural's person sex life or sexual orientation*" are considered "sensitive"[3]. Controllers can only process these data if they respond to the requirements listed under article 9(2), *inter alia* the explicit consent of the data subject or public interest.

Henceforth, **data subjects have the right to obtain information about all processing activities, how the data are being controlled, monitored or used further**, in order to enable transparency and control over their data.

Generally speaking, consent given in written form is the standard practice in the field of research, although consent can also be given orally or digitally. The PROACTIVE consortium must draw up comprehensive Information Sheets and written Consent Forms that include the information required by the GDPR conveying it in a way that is clear and comprehensible for the kind of participants to be involved in the field exercises, allowing them to give consent compliant with the GDPR. The information that must be provided to data subjects when their personal data will be collected directly from them can be found in Article 13 GDPR:

1. Where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:

*(a) the **identity and the contact details of the controller** and, where applicable, of the controller's representative;*

*(b) the **contact details of the data protection officer, where applicable**;*

*(c) the **purposes of the processing** for which the personal data are intended as well as **the legal basis for the processing**;*

(d) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;

*(e) the **recipients or categories of recipients of the personal data**, if any;*

[2] Article 4 GDPR

[3] Article 9 GDPR

*(f) where applicable, the fact that the controller intends to **transfer personal data to a third country or international organisation** and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.*

2. In addition to the information referred to in paragraph 1, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:

*(a) the **period for which the personal data will be stored**, or if that is not possible, the criteria used to determine that period;*

*(b) **the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;***

*(c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the **right to withdraw consent at any time**, without affecting the lawfulness of processing based on consent before its withdrawal;*

*(d) the **right to lodge a complaint with a supervisory authority;***

(e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;

(f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

3. Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2.

4. Paragraphs 1, 2 and 3 shall not apply where and insofar as the data subject already has the information.

However, if people present who have a vulnerability preventing them from giving their Informed Consent in written form (for example, a visual disability), the consortium will have to find alternative methods enabling these people to give consent. For example, if individuals with a visual impairment take part in field exercises, they could be provided with the necessary information and give their Informed Consent orally (Recorded Audio Consent). This consent should be recorded and witnessed for validation if needed.

As far as minors are concerned, Article 8 of GDPR establishes the following:

> *the processing of the personal data of a child shall be lawful where the child is at least 16 years old. Where the child is below the age of 16 years, such processing shall be lawful only if and to the extent that consent is given or authorised by the holder of parental responsibility over the child.*
>
> *Member States may provide by law for a lower age for those purposes provided that such lower age is not below 13 years.*

The Article gives an idea of how European legislation approaches age relating to Informed Consent.

As far as the age at which people can give consent for the processing of their personal data, the four possible host countries in which PROACTIVE had the option to hold its field exercises have different criteria. The following table provides information on the age at which people can provide consent for the use of their personal data in general in the different countries and the age at which these countries plan to allow children to give consent to the processing of their personal data.

Table 1: Minimum age for giving informed consent

Country	Minimum age (information services)
Italy	14
Poland	16
Germany	16
Belgium	13

Source: Own elaboration (data coming from the Better Internet for Kids).[4]

Regarding this issue, ETICAS and CBRNE will take a conservative approach and recommends the following:

[4] https://www.betterinternetforkids.eu/en_US/web/portal/practice/awareness/detail?articleId=3017751

- **The involvement of people under the age of 18 adds value to the research; accordingly appropriate safeguards must be put in place** especially in terms of ensuring they understand their participation in the exercises.
- Consent must be obtained in a way that accounts for the fact that minors may be more vulnerable or easily manipulated than adults, which means the PROACTIVE consortium will need to put in place measures preventing deliberate or accidental coercion from taking place.
- Assent procedures and specific aged adapted information sheets will be developed in order to guarantee that the minors are adequately informed;
- For anyone under the age of 16 (possibly 18 depending on the country) parental consent is required. Recruited volunteers under the age of 16, should sign an assent form, and in addition their parent/guardian should sign confirming consent on their behalf.

In summary, PROACTIVE needs to adequately justify the reasons that call for the participation of minors and take a stricter approach to Informed Consent by both the minor and his or her parent(s).

Table 2: Actions to safeguard the protection of minors

Action to safeguard the participation of minors	Organisation responsible
Civil Society Advisory Board should be involved throughout the organisation process	PROACTIVE
Management of the inclusion/ exclusion criteria when selecting the volunteers	PROACTIVE
PROACTIVE consortium must be briefed by eNOTICE regarding the security measures put in place and risks the field exercises may involve in order to be able to provide accurate and updated information to research participants	eNOTICE
Management of the Risk Table	PROACTIVE
Management of the “Informed Consent” process	PROACTIVE
Get parental authority for volunteers under the age of 18.	PROACTIVE
If minors (aged <16 or <18, depending on the country) are involved in the exercises, additional measures aimed at ensuring their integrity and safety must be put in place, especially in terms of ensuring they understand what their participation in the exercises involves and that coercion is not being exerted.	PROACTIVE

The detailed procedures for research ethics requirements are described in Deliverable D7.4 *Data Management Plan and Research Ethics*, in special section 5 *Ethical Research* (section 5.6 *Research Ethics Protocol*) and in D10.6 *Protection of Personal Data Requirement no 6: Informed Consent procedures and templates*.

The following templates of the Research Ethics Protocol are attached as annexes for use during the field exercises:

- A1: PROACTIVE *Research Ethics Protocol Cover Sheet*
- A2: PROACTIVE *Informed Consent Form*

- A3: PROACTIVE *Information Sheet*
- A4: PROACTIVE *Consent form for photo/video activities*
- A5: PROACTIVE *Dataset Template*

The templates for Information sheet and consent form are adapted for PROACTIVE use following the format recommended by University of Oxford Research Ethics Committee, available at https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#collapse1670841

For details regarding the management of the Informed Consent prior to and during the field exercises, see section 4.3.

3.2.3. Data Management

Data management is composed of the following parts:

- Data collection;
- Data storage;
- Data protection;
- Data sharing/transfer;
- Data retention/destruction.

All these elements are addressed within D7.4 *Data Management and Research Ethics.* However, there are three legal precepts that should be taken into consideration by partners regarding data management, given their importance.

- **Article 25:** "Data protection by design and by default", including procedures for pseudonymisation and data minimisation. Article 25 of GDPR establishes that, after performing a contextual analysis of the risks that can be caused by processing, appropriate data protection measures must be put in place. This obligation has been fulfilled by the deliverable D10.7 *Protection of Personal Data: Requirement no 7*, which takes stock of the personal data collected within the context of PROACTIVE and the preventative measures adopted to mitigate the risks associated with their processing.

- **Article 30:** "Record of processing activities", according to which an accurate description of the processing activities shall be kept by the data controller and the data processor and, upon request, made available to supervisory authorities. Article 30 GDPR establishes the obligation to keep a record of processing activities. This obligation does not always apply. Article 5 establishes the situations in which the obligation of keeping records will apply in the following manner:

  The obligations referred to in paragraphs 1 and 2 shall not apply to an enterprise or an organisation employing fewer than 250 persons unless the processing it carries out is likely to result in a risk to the rights and freedoms of data subjects, the processing is not

occasional, or the processing includes special categories of data as referred to in Article 9(1) or personal data relating to criminal convictions and offences referred to in Article 10.

Considering the field exercises, the partners processing personal data belonging to special categories (among them CBRNE, PHE, and DHPol) will need to keep records of the processing activities involving data belonging to special categories. The specifics of this requirement are presented in D10.5 Protection of Personal Data *Requirement no 5*, which describe the technical and organisational measures implemented to safeguard the rights and freedoms of the data subjects/research participants.

- **Article 32:** "Security of processing". This article aims to ensure the data processor and data controller process and securely keep the data to avoid data being destroyed, lost, altered, disclosed or accessed in an accidental or unlawful way. Article 32 GDPR, states the controller's obligation to ensure data are kept in a secure manner. The measures adopted to ensure compliance in this sense are included in D10.2 *Protection of Personal Data Requirement no 2* and the D7.4 *Data Management Plan and Research Ethics.*

As shown in sections 3.2.1 – 3.2.3, the roles between PROACTIVE and eNOTICE are clearly defined regarding the design, implementation, analysis and exploitation of results of the joint exercises. PROACTIVE is responsible for its own data collection, analysis and exploitation of archived results which will ensure that PROACTIVE objectives and impact are met. In addition, PROACTIVE will make sure that the selected joint scenario with eNOTICE and the study design is relevant for the PROACTIVE Strategical and Tactical objectives. More information about the roles of the two projects with respect to the study design and implementation during the three field exercises are provided in D6.1 and D6.2.

3.3. Research ethics

International standards and requirements for research with human subjects have been established since the beginning of the second half of the 20th century. In particular, the Nuremberg Code (1947), the Declaration of Helsinki (1964), and The Belmont Report (1979) provide key references in this regard. The Nuremberg Code underlined the need for guaranteeing and respecting the voluntary nature of human participation in research and pointed out the requirement of establishing mechanisms for Informed Consent, also ensuring people involved in research can withdraw from it at any time. This code also underlined that researchers must ensure the welfare and protect the interests of participants. With this aim in mind, researchers must establish in advance mitigation measures for addressing any risk of harm for them. The Declaration of Helsinki followed the same approach. Conversely, the Belmont Report developed four key ethical principles to be considered when carrying out research activities:

- **respect for people:** research subjects must be treated so as to protect their safety, respect their autonomy and ensure their consent on an informed basis;

- **beneficence:** possible benefits for the participants will be maximised while possible harm or risk will be minimised;
- **justice:** any benefits and burdens derived from research must be balanced;
- **competence**: the limitations and boundaries of the researchers' competence must be recognised and made explicit.

In respect to research ethics, project PROACTIVE has established a comprehensive governance framework, underlined by the D 7.4 D*ata Management Plan and Research Ethics*, in special section 5 *Ethical research*.

As detailed in D8.1 during the planning phase and the implementation of the PROACTIVE joint field exercises, the consortium will strive to implement the seven ethical goals *designed to inform both the content of preparedness plans and the process by which they are devised, updated, and implemented* (Jennings and Arras, 2008)*:*

1. **Harm reduction and benefit promotion.** Emergency preparedness activities should protect public safety, health, and well-being. They should minimise the extent of death, injury, disease, disability, and suffering during and after an emergency.
2. **Equal liberty and human rights.** Emergency preparedness activities should be designed so as to respect the equal liberty, autonomy and dignity of all persons.
3. **Distributive justice.** Emergency preparedness activities should be conducted so as to ensure that the benefits and burdens imposed on the population by the emergency and by the need to cope with its effects are shared equitably and fairly.
4. **Public accountability and transparency.** Emergency preparedness activities should be based on and incorporate decision-making processes that are inclusive, transparent, and sustain public trust.
5. **Community resilience and empowerment.** A principal goal of emergency preparedness should be to develop resilient, as well as safe communities. Emergency preparedness activities should strive towards the long-term goal of developing community resources that will make them more hazard-resistant and allow them to recover appropriately and effectively after emergencies.
6. **Public health professionalism.** Emergency preparedness activities should recognise the special obligations of certain public health professionals, and promote competency of and coordination among these professionals.
7. **Responsible civic response.** Emergency preparedness activities should promote a sense of personal responsibility and citizenship.

4. MANAGEMENT OF VOLUNTEERS IN AN ETHICAL MANNER

4.1. Criteria for identification and recruitment of research participants (including vulnerable groups)

One of the objectives of PROACTIVE is to identify potential shortcomings in existing procedures, technologies, and technical tools with respect to citizens, including members of vulnerable groups. The sample of volunteers participating in research activities, including field exercises, needs to include people with vulnerabilities for it to be useful and in line with the vulnerable citizens' lived experiences. In this respect, Task 3.2 *Identification and organisation of vulnerable group participation* will define and select research participants in collaboration with representatives of vulnerable categories within the Civil Society Advisory Board (CSAB) and the organisations responsible for organising field exercises. Task 3.2 will inform the consortium's admission and exclusion criteria to justify the participation of vulnerable categories of the population and their role in the project.

PROACTIVE exercises aim to include 10% to 15% of vulnerable people from the total number of the volunteers involved. The DoA defines vulnerable citizens in the following way:

> these are members of the public but specifically including citizens with needs that differ from the average population such as persons with **disabilities**, the ill (e.g. with chronic or acute health conditions), **elderly**, or members of an **ethnic minority** or of a **vulnerable group**. Vulnerable groups may include **children**, **pregnant women**, persons with disabilities, chronic medical disorders or addiction, older persons with functional limitations and health restrictions, institutionalized individuals as well as their carers and companions. Vulnerable citizens also include persons with **limited proficiency of the respective national languages** or with **restrictions regarding use of transportation**.

Accordingly, the participants in the field exercises will be 85% to 90% with no apparent vulnerabilities and 10% to 15% with vulnerabilities having to identified by one of the following factors:

- Disability status;
- Age (Minors and the elderly);
- Mobility;
- Language proficiency including those with language difficulties who may be i) those who do not speak/understand the language native to the country of the field exercise and/or ii) those who may have difficulty understanding the language (even their native one) due to aphasia for example. Some may have both difficulties as well as others; or
- Members of the public assessed as being vulnerable which might include ethnic minorities, pregnant women, a child detached from its parents etc.

The criteria for the selection of participants in research activities (volunteers) and the profile and size of volunteer groups (including vulnerable groups) have been discussed and agreed by the

consortium partners involved in the research (PHE, UMU, DHPOL, ETICAS, CBRNE, UIC) In this respect, the partners have agreed:

- The number of volunteers participating in each exercise will be established through discussions with the organisers of the particular exercise taking place. The group size might vary, based on the chosen scenario and logistical limitations and with a minimum of 25 to a maximum of 150 volunteers. The volunteers with apparent vulnerabilities will represent a minimum 10% -15 % of the total number. The final list of subpopulations categories will be shared with the EEAB for its examination.

- The methodology for establishing the criteria for selecting the volunteers (including the vulnerable groups) will be based on the functional needs approach (Kailes et al., 2007). This approach leads to a common framework that "can relate functional support to functional needs, targeted at improving resource management in any type of incident" (idem, p.232). The authors propose a flexible framework built on five function-based needs: communication, medical needs, maintaining functional independence, supervision and transportation (C-MIST). Addressing functional limitations includes both people who identify as having a disability and "the larger number of people who do not identify as having a functional limitation in hearing, seeing, walking, learning, language and/or understanding" (idem, p.234). The functional needs approach has been used with good results by PHE (Carter & all, 2016) to review and update the guidance documents for mass casualty decontamination, including vulnerable groups. The following table characterises 14 vulnerable groups that PROACTIVE focuses on, based on 7 vulnerability criteria that might apply (Usher, 2014):

Table 3: Vulnerability criteria

Vulnerability / Groups	Reduced mobility	Lack of autonomy	Ignorance	Poor health	High public profile	Societal margina-lisation	Obligation towards others
Minors		✓	✓				
Older people	✓	✓		✓			
Women						✓	
Pregnant women	✓						✓
Migrants			✓			✓	
Displaced people						✓	
Low-income people			✓			✓	
Homeless people		✓		✓		✓	

Illiterate people			✓			✓	
Isolated people						✓	
Institutionalised people		✓				✓	
Physically disabled people	✓	✓		✓		✓	
People with learning difficulties		✓	✓			✓	
People with acute medical conditions	✓	✓		✓		✓	
Carers		✓					✓
Emergency services personnel							✓
Politicians					✓		✓

All the above forms of vulnerability indicate some sort of precariousness in the condition of the project participants. For Kipnis (2001:5), it indicates a "state of being laid open or especially exposed to something injurious or otherwise undesirable". Therefore, the degree and form of each of the above groups' vulnerability will depend on the exposure to certain environmental, physical or mental conditions or situations. In this way, while ignorance or social margination can be addressed through accurate and clear informed consent protocols, other subpopulations vulnerable conditions may require specific instruments, measures or prevention strategies. Based on the current discussions that we had with the eNOTICE exercise hosts, we do not expect to integrate homeless individuals into the field exercises, but other categories such as children and people lacking physical autonomy are very likely to be involved. In this framework, people with accurate needs among the research sample only include physically disabled people. This will require following the assent protocol and environment and safety specifications established in D8.3 and D10.6 to be updated in the test plans and discussed in the pre-exercise training activity.

4.2. Guidelines for selecting volunteers to 'role play' disaster victims

Using people to 'role play' disaster victims or other roles can add realism to an exercise. However, it does add an extra element of risk that PROACTIVE needs to manage.

When selecting people to role play, the following should be considered (AIDR, 2012):

- Some individuals may react adversely to receiving 'moulage' (make-up simulating injuries) and being placed in a scenario that might cause them to recall painful experiences. Exercise

managers should ensure appropriate debriefing and psychological first aid is available if required;

- Role players should fully understand the nature of the required role;
- Role players should not have experienced a major incident in the past that is still a sensitive issue for them;
- Role players should not have existing medical condition that could be exacerbated by the participation during the exercise such as asthma, epilepsy, blood pressure anomalies, cardiac conditions, back problems, sensitive skin or claustrophobia.
- Role players should not be on medication that may affect their role;
- Exercise staff should investigate the respective workplace/occupational health and safety legislation or other relevant legislation to determine the extent to which their duty of care applies to role players and obtain advice about issues such as insurance coverage.

4.3. Ethical principles guiding the recruitment of the research participants

The PROACTIVE Project Ethics Officer (PEO) reviews the recruitment methods and materials for all studies and activities in consideration of the purpose of the research.

As mentioned in D8.1, Researchers should consider the following ethical issues (Purdue University 2014, Iowa State University 2016) when planning their recruitment strategies:

- Respect for privacy: In some cases, simply being invited into a study may involve privacy concerns. For example, sending an email or leaving a voice message inviting an individual to take part in a study of individuals with a specific disease or stigmatising condition may "out" them to others. Recruitment methods must take into account privacy concerns. Participants in PROACTIVE studies will receive complete and accessible information on data collection and processing. A summary of the types of sensitive data that are going to be collected within PROACTIVE can be found in D7.4. The sensitive data used for research purposes will be processed on the basis of informed consent in all cases. Further information on the participant's data protection is to be found in D7.4, and in D10.6 *Informed consent procedures and template*.
- Equitable selection of participants: The recruitment ensures the selection of research participants is equitable and appropriate for the study.
- Unbiased presentation: All information used for recruitment should be accurate, balanced, and free of misleading emphasises that make the study excessively attractive. Number of visits, expected time commitment, any eligibility criteria, etc., should fully align with the proposed research plan. Information must be clear and understandable, and free from technical or scientific jargon.
- Lack of pressure or undue influence: The study is introduced to potential participants in a way that allows them ample time to consider, with no undue pressure because of the *timing*

of the request, *who* makes the request, *how* the request is made, or the offering of excessive inducements.

- Respect for persons: The recruitment ensures appropriate procedures are used for the study participants, especially if the participants include vulnerable populations such as children, pregnant women, older persons, economically disadvantaged persons and cognitively impaired persons or those lacking in decision-making capacity. Other participants may be considered a vulnerable population depending on their circumstances in relation to the research.

Right to withdraw: Participants have the right to withdraw at any moment without giving any reason.

Due to the nature of volunteers' participation in the PROACTIVE field exercises, distress might be expected among some participants. In such cases, participants will be able to pause or stop their participation at any time and without justification.

The procedures used to identify/recruit research participants are described in D10.1 *H - Requirement no 1*.

4.4. Management of Informed Consent

All participants in PROACTIVE field exercises will be given information sheets attached to their Consent Forms setting out clearly what is expected of them as part of the exercise instruction package. The Exercise Briefings (annexes to the Exercise Action Plan) will be tailored to the roles of the individual participants.

The Consent and Assent Forms drafted in the local language for signature by volunteers prior to and on the day of the respective field exercise will comply with requirements established in D10.6 *Requirement no 6 Informed Consent procedures and templates* and adapted to meet the objectives of the exercise itself. The following is a selection of these guidelines relevant to Project PROACTIVE field exercises:

- a statement that the exercise involves research participants, an explanation of the purposes of the research and the expected duration of the subject's participation, and a description of the procedures to be followed;
- a short explanation of the recruitment method and participants' selection rationale;
- a description of any reasonably foreseeable risks or discomfort to the subject;
- a description of any benefits to the subject or others which may reasonably be expected from the research;
- Insurance guarantees provided to participants;
- for research involving more than minimal risk, an explanation as to whether there are any treatments or compensation if injury occurs and, if so, what they consist of, or where further information may be obtained;

- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- an explanation of whom to contact at any time for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation. In case that the volunteer decided to withdraw from the activity, he can request to have the personal data relating to him removed, and the request will be granted by the data controller.

D7.4 *Data Management Plan and Research Ethics,* Section 5.6 Research Ethics Protocol provides the templates for the Consent Form and Information Sheet.

4.5. Briefings

The Exercise Action Plan established following the IIMARCH framework (D6.1) will set up a procedure for participants to be briefed in person immediately (e.g.one hour) prior to commencement of a Field Exercise to allow opportunity for final questions to be asked and to ensure participants are fully aware of their roles.

These briefings will be split into (i) Pre-Exercise Play; (ii) Activation Phase and (iii) Dynamic Role Play (i.e. free play) and (iv) Directing Staff interaction, as necessary.

4.6. Welfare support

The Exercise Action Plan established following the IIMARCH framework (D6.1) will outline all welfare support available to participants in field exercises (transport, reception, food and breaks). The schedule for the reception of all exercise participants will be published in an information sheet for participants and will set out the specific locations and facilities for each type of participant: Volunteers; Planners; Mentors; Evaluators; Observers.

4.7. The right to withdraw

The right to withdraw without giving a reason is specified in the Consent Forms. This will in no way affect the care that the participants will receive during and following the field exercise. In addition, they will each be reminded of this right during the briefing sessions mentioned above. In case that the volunteer decided to withdraw from the activity, he can request to have the personal data relating to him removed, and the request will be granted by the data controller.

5. INSURANCE COVER

Insurance will ensure that through the different organisations that control the volunteers there is sufficient means to cover all eventualities.

The field exercises will need to consider Public Liability Insurance, Employer's Liability Insurance, cancellation and abandonment, terrorism, adverse weather, communicable diseases, national mourning, travel management, and may also be needed to insure property and equipment hired or owned by third parties. Initially the host organisers need to be consulted to identify their existing insurance to ensure there is no duplication. It should be noted that until there is a better understanding of proposed scenarios and actions forming the field exercises it is difficult to understand whether the legal and ethical actions required are the responsibility of:

- The host organisation (i.e. eNOTICE);
- The guest organisation (i.e. PROACTIVE);
- A combination of the two organisations.

Each field exercise will have specific arrangements that will be outlined in the Exercise Action Plan.

6. HEALTH AND SAFETY

The substances used during the trials to simulate the relevant scenario of a chemical, biological, or radiological event are to be handled by the eNOTICE consortium. Thus, the PROACTIVE consortium must work closely with eNOTICE to ensure international standards and norms are respected during research activities. The PROACTIVE consortium must be aware of the security measures put in place and risks the field exercises may entail to provide accurate and updated information to research participants on the nature of their proposed activities, and, eventually, to adopt the necessary measures to guarantee that the impact on their physical and psychological integrity is minimised.

The scenarios of the field exercises will remain only partially known to the volunteers so the following circumstances may affect participants during the field exercises. The table below groups the various risks into several categories and suggests mitigating measures aimed at lowering the risk for participants, especially those who are vulnerable:

Table 4: Risk Table

Testing conditions	Mitigating measures
Transport/Inconveniences	
1. Participants will travel to the exercise using their own transport, public transport or perhaps transport that has been provided to help for instance disabled or vulnerable volunteers.	1. Participants should be made aware of the transport conditions before they agree to take part (at the moment of giving consent). 2. Participants should be asked to bring swimming suits in case they need to be

2. There may be the need to undress (down to under garments) to be showered. 3. Participants may experience prolonged periods of waiting, which might be tiring. 4. Some participants may have difficulties with access to some areas.	showered. Appropriate changing facilities should be provided to preserve participants' dignity. 3. On top of informing participants about the duration and nature of the trials, some way of relaxing or passing time should be provided, especially for those more likely to be bored or distressed (children). 4. Organisers should consider making appropriate arrangements for access for those with physical disabilities. 5. Organisers may have to provide special showering facilities to cater for i) disabilities and/or ii) matters of decorum / social prudence
Health	
1. The project will be giving all volunteers sustenance (food and drink), so there is a possibility of food poisoning. 2. The weather may lead to freezing, wet and miserable conditions, or conversely, it may be very hot and lead to dehydration, sunstroke and sunburn.	1. Food and drinks must be in good state and kept in proper conditions. Medical personnel should be prepared for treating people affected by food poisoning. 2. Medical assistance should be available at all stages of the field exercise. 3. Participants are likely to be local, but in any event both local and foreigners should be briefed on the weather conditions of the field exercise sites and advised on how to be properly equipped. 4. Medical personnel should be prepared to deal with cases of hypothermia, heatstroke and/or sunburn. 5. Warm areas and blankets should be available if the weather is likely to be cold. 6. Infrastructure should be in place to provide shelter if necessary. 7. All participants but especially foreigners and vulnerable individuals (old people, people with certain conditions) should be briefed on the importance of staying hydrated.
Privacy	
1. There will be media attention involving photographs and filming and perhaps journalists who will want to interview the volunteers	1. Although data gathered by the media will not be processed by the consortium, there is a need to have a system in place for managing media involvement which may involve journalists interviewing the

2. Participants' personal data, including videos and images collected during the exercise, could be made public by the project partners.	volunteers. Participants need to be made aware of (and consent to) any photographs/ filming undertaken as part of the exercise, and any media involvement needs to be very carefully managed – a plan needs to be in place for this beforehand. 2. All participants will be required to sign a consent form detailing the data management requirements. The project partners will publish only anonymised data collected from the exercises as part of the project.
Language barriers	
1. The volunteers will be briefed by the organisers – this could lead to misunderstandings. 2. There will be language barriers between the international organisers and the local volunteers.	1. If the briefing addresses matters of vital importance, the oral briefing should be accompanied by a written note in the participants' mother tongue to avoid misunderstandings. It may be necessary to provide oral and sign language instructions on a one to one basis in their native language (if existing written instructions cannot be understood) – in the event that not all participants can understand both written and general verbal instructions 2. All participants, with some emphasis on international participants, have to be made aware that they may not understand instructions at certain stages and that this forms part of the simulation.
Physical integrity	
1. There will be heavy equipment in the vicinity. 2. There may be handling of volunteers by the Practitioners (i.e. lifting, guiding). 3. There will be site-specific hazards leading to physical injury 4. Some participants will be psychically impaired.	1. Participants must be kept away from heavy equipment. 2. Practitioners must be told to handle volunteers in a way that is respectful and proportional to the situation, as well as adapted to the vulnerabilities or specific circumstances of certain participants. Proportionality is important as it must be accepted (in the Consent Form) that the act of "pushing and shoving" will involve necessary personal contact by the LEA as part of their normal procedures for guiding and moving civilians in an emergency. 3. A site-specific safety briefing must be provided outlining areas of risk. Areas

	out of bounds should be clearly identified and cordoned.
Psychological integrity	
1. During the exercise there may be loud bangs, smoke and other distractions to help bring realism to the scenario. These may frighten people. 2. There may be distressing play acting volunteers could find offensive or upsetting. i.e. an actor might show signs of asphyxiation (losing breath) or there may be imitation blood. 3. There may be shouting and screaming.	1. Since such circumstances need to take place in order for the field exercises to achieve its objectives, we advise to let participants know distressing situations may come about, but they have to keep in mind the situation is under control at all times. This information should be provided in advance of the exercise thus allowing individuals to make an informed decision on whether they wish to participate
Vulnerable people	
1. There will be vulnerable people with special needs. The organisers will of course plan for looking after these individuals but there may be unforeseen situations difficult to deal with.	1. Vulnerable people should be briefed on those circumstances most likely to affect them as well as on appropriate mitigating measures, and organisers should be aware of the different circumstances that could come about and the protocols to be followed. 2. Organisers should ensure emergency services and first aiders (other than those participating) are aware of the potential for the presence of vulnerable people. 3. Carers or assistants should also be appropriately briefed.
Security Issues	
1. The exercise sites are secure compounds with restricted public access	1. Participants should be vetted as suitable to attend and be briefed in respect of access into restricted areas. 2. Appropriate measures should be put in place to cordon restricted access areas.

The table above is for guidance only. Stakeholders should prepare their own risk assessments and ensure both eNOTICE and PROACTIVE are mutually kept informed.

The D6.1 and the Exercise Action Plan established following the IIMARCH framework will consider the risks identified based on the planned exercises routines and will be supported through a series of appendices giving instructions to mitigate these risks. Therefore, it is accepted that local

processes will be adopted and supported by a PROACTIVE checklist template that identifies that a Risk Assessment exists. An example is shown in Annex 1 of D6.1. One of the key points of focus for the Risk Assessments will be to ensure that the special needs of vulnerable groups have been appropriately assessed and addressed. The Risk Assessment section will incorporate a Risk Register covering the exercise in general, which will assist in both minimising the impact and informing the Contingencies element of the Method section. In addition, the Risk section will also cover risks associated with the location, activity undertaken, identified groups of people, the environment, and financial and legal aspects. This list is not exhaustive and will vary between locations and countries. A risk register has been established and the risks relating to the COVID-19 pandemic have been incorporated.

7. ETHICS SUPERVISON DURING THE FIELD EXERCISES

To provide ethical oversight during the PROACTIVE field exercises, the Ethics and Data Protection Supervisor (EDPS) has been appointed. The role is fulfilled by the Project Ethics Officer of project PROACTIVE, Dr Irina Marsh (CBRNE).The role of EDPS is to ensure field exercises are carried out in a manner that is ethically compliant with the relevant legislation set out in Section 3 of this document and will carry out an on-site evaluation of ethical aspects of the exercise seeking to ensure, in particular that:

- the Exercise is being carried out with respect for human dignity at all times;
- all proper authorisations have been obtained;
- the exercise briefings have been carried out in accordance with recommendations;
- volunteers have completed a consent form(s) as recommended;
- relevant legislation has been complied with.

The EDPS will be supported by the External Ethics Advisory Board (EEAB) members. The EEAB members will provide a consultative role for the exercise planning team and:

- will provide advice and guidance on the conduct of the exercise where it relates to the management of the volunteers, safety and risks;
- will review materials and advice on their content (e.g. information sheets, consent forms etc.);
- will work in close relation with the EDPS, exercise planning team and emergency services participating in the exercise.

The EDPS and EEAB members will support the ethics evaluation of the field exercises, part of the Task 8.4 *Ethical and Societal Assessment of PROACTIVE outputs*. In this respect, The EDPS and EEAB will follow the *Ethical impact assessment framework* established in D8.1 (sections 3.4 and 3.5) and the associated ethical tools:

- *Ethics Evaluation Template;*
- *Ethics Checklist for Tool Providers;*
- *Ethics Impact Assessment of CBRNE procedures and tools on vulnerable people.*

The *Ethics Evaluation template* (Stănciugelu et al., 2014) is constructed as a package of interdependent values that underline the work of response teams and emergency medical staff when confronted with disaster situations. The values and principles overlap with the principles drawn from fundamental rights as presented in previous sections, as they share the same philosophy – the ethics embedded in the Declaration of Human Rights.

The *Ethics Checklist for Tool Providers* (Stănciugelu et al., 2014) serves as a heuristic tool. It provides the user with a framework to identify potential ethical issues associated with CBRN response tools. This is important because CBRN responses have traditionally been treated as primarily a technical and/or organisational challenge where technological advances were either generally understood as something positive or seen through a purely consequentialist ethical lens (that is: means and right secondary as long as outcome positive). However, CBRN response tools raise a wide range of issues touching upon the fields of disaster management ethics (e.g. individual liberty versus collective protection from cross-contamination), technology-related ethics (e.g. track& trace and privacy/data protection), research ethics (e.g. how to organise realistic exercises without violating rights of physical integrity), and others.

The *Ethics Impact Assessment of CBRNE procedures and tools on vulnerable people* explores the impact of CBRNE tools and procedures on 'vulnerable groups' (Usher, 2014). It considers the causes, nature and extent of the impact, and examines whether it is possible to predict its social and cultural aspects. The author created a protocol that supports the impact assessment process and provides recommendations for mitigating any negative effect of the tool on vulnerable people.

8. FURTHER DEVELOPMENT OF D8.3 AND ASSOCIATED ACTIVITIES

D8.3 is issued as a Guideline for use by PROACTIVE Practitioners carrying out joint exercises. As the planning process for the field exercises is advancing, for each field exercise the guidelines presented in this document will be adapted to specific protocols, procedures and documents and will become part of the Exercise Action Plan which will be established following the IIMARCH framework in D6.1. The EEAB will guide, supervise and approve the further reiterations of the document.

As part of Task 8.3, based on this document, the PROACTIVE consortium members will receive training on how to detect and tackle privacy and ethical issues during the design and deployment of the exercises. Moreover, an updated version of the recommendations made in this deliverable will be created during an evaluation workshop conducted after each exercise.

Under Task 8.4, after the implementation of the PROACTIVE field exercises, D8.3 and the associated protocols, procedures and documents part of the Exercise Action Plan will inform the creation of the D3.2 *Aide Memoire for future exercises or demonstrations involving vulnerable groups.* D3.2 will also be informed by our work with the preparation of field exercises in terms of civil

society involvement, and framed and presented as instruments that may be exploitable in similar research contexts and scenarios. All these documents will be ready for use in case a serious gaming workshop can be organised towards the end of the project. Although PROACTIVE does not focus on delivering training or serious gaming activities during the lifetime of the project, these will be considered for training and awareness-raising purposes with members of CSAB and PSAB.

9. CONCLUSIONS

This document has been written for practitioners and researchers taking part in the eNOTICE and PROACTIVE joint action field exercises to give a good understanding of the main legal and ethical norms by which they have to abide. It aims at ensuring basic legal and ethical norms applicable in the host country are considered when designing and conducting the exercises.

This document highlights issues related to ethics research and management during the PROACTIVE field exercises. The document provides the necessary framework on ethical management of the participants, including vulnerable citizens, focusing on recommendations regarding privacy and data protection rights, Informed Consent, health and safety considerations and ethical supervision of the exercises.

As the planning for each field exercise progresses the guidelines presented in this document should be adapted to specific protocols, procedures and documents and will become part of the Exercise Action Plan.

Based on this document, the PROACTIVE consortium members will receive training on how to detect and tackle privacy and ethical issues during the design and deployment of the exercises. Moreover, an updated version of the recommendations made in this deliverable will be created during evaluation workshop conducted after each exercise.

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11. ANNEX 1 – PROACTIVE RESEARCH ETHICS PROTOOL COVER SHEET

Submission for Ethical Review and Approval

Please complete this form digitally and send it to the PROACTIVE Project Ethics Officer, Dr Irina Marsh (irina.marsh@cbrneltd.com) and include in cc Martin Mariano Zamorano (martin@eticasconsulting.com) one week prior use.

Date of Submission: Enter the date here.

Work package/Task number: Enter the title here.

Name(s) of researcher(s): Enter the name(s) here

Name of institution (if applicable): Enter the name of the supervisor here. Telephone number:

Enter your telephone number here.

E-mail address: Enter your e-mail address here.

RESEARCH

R.1. What is the research question? Please indicate what scientific contributions you expect from the research.

Enter your research question here.

R.2. What type of research is involved?

☐Questionnaire

☐Interview

☐Experiment

Other, namely: Enter the type of research here.

R.3. Where will the research be conducted?

☐Online

☐At the institution

☐Non-institution setting: Enter which setting here.

Other, namely: Enter where the research will be conducted here.

R.4. If the research is experimental, what is the nature of the experimental manipulation?

Enter the nature of the experimental manipulation here.

R.5. Why is the research task important? What benefits may result from the study?

Enter the importance of the research here.

R.6. Are there others project's partners involved in the research? If so, please name them and describe the way they are involved in the research.

Enter information on project's partners here.

R.7. Are there others stakeholders involved in the research? If so, please name them and describe the way they are involved in the research.

Enter information on other stakeholders here.

R.8. Are there partners from a third country involved in the research? *Will personal data be shared* with these 3rd parties? If so, please describe the data protection arrangements.

Enter information on partners from a third country here.

PARTICIPANTS

Pa.1. What is the number of participants needed? Please specify a minimum and maximum.

Minimum: Enter the minimum here.

Maximum: Enter the maximum here.

Pa.2.a. Does the study involve participants who are particularly vulnerable or unable to give informed consent? *(e.g., children, people with learning difficulties, old people, people with disabilities, etc)*

Enter whether or not participants can give informed consent here.

Pa.2.b. If yes and unable to give informed consent, has permission been received from caretakers/parents?

Enter if permission from the caretakers/parents can be received here.

Pa.3. Will the participants (or legal guardian) give written permission for the research with an 'Informed Consent' form that states the nature of the research, its duration, the risk, and any difficulties involved? If no, please explain.

Enter your answer here.

Pa.4. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children or students)? If yes, please explain.

Enter the participant's position here.

Pa.5. How much time in total (maximum) will a participant have to spend on the activities of the study?

Enter the amount of time here.

Pa.6. Will the participants have to take part in multiple sessions? Please specify how many and how long each session will take.

Enter how many sessions a participant has to attend here. Pa.7. What will the participants be asked to do?

Enter your answer here.

Pa.8. What are the possible (reasonably foreseeable) risks for the participants? Please list the possible harms if any.

Enter the risks for the participants here.

Pa.9. Will extra precautions be taken to protect the participants? If yes, please explain. Enter which extra precautions will be taken here.

Pa.10. Are there any positive consequences for a participant by taking part in the research? If yes, please explain.

Enter any positive consequences here.

Pa.11. Will it be made clear to the participants that they can withdraw their cooperation at any time? Enter your answer here.

Pa.12. Where can participants go with their questions about the research and how are they notified of this?

Enter to whom participants can address their questions here.

Pa.13. Will the participants receive a reward?

☐Travel expenses
☐Compensation per hour
☐Nothing
Other, namely: Enter the reward here.

Pa.14. How will participants be recruited?

Enter how participants are recruited here.

PRIVACY

Pr.1. Are the research data made anonymous? If no, please explain.

Enter whether or not the data is made anonymous here.

Pr.2. Will directly identifiable data (such as name, address, telephone number, and so on) be kept longer than 6 months? If yes, will the participants give written permission to store their information for longer than 6 months?

Enter how long the data will be stored here.

Pr.3. Who will have access to the data which will be collected?

Enter who has access to the data here.

Pr.5. Will covert methods be used? *(e.g. participants are filmed without them knowing)*

Enter if covert methods will be used here.

DOCUMENTS

Please ensure that, where appropriate, the following documents are submitted along with your application:

- A summary of the research task detailing who is doing what, to whom, to how many, where, when and why in non-technical, lay terms
- Copy of the Information Sheet for participants (on letterhead) Copy of the Consent Form (on letterhead)
- Copy of questionnaire/interview content &schedule
- Copies of standard letters related to the project (on letterhead)
- Copy of risk assessment (if applicable)
- Evidence of insurance cover/indemnity (if applicable)
- Copy of draft email recruitment advert/poster (remember to include statement confirming favourable ethical opinion)
- Information concerning any other Ethical Committee (e.g. institutional, national) to which an application for ethical opinion is being /has been made

12. ANNEX 2 – PROACTIVE INFORMED CONSENT TEMPLATE

Optional statements are highlighted turquoise – delete entire table row if not applicable to your study and re-number remaining rows (then delete this advisory text)

PARTICIPANT CONSENT FORM

PROACTIVE Project Ethics Officer Approval Reference: xxxxx

[Research activity Title]

Background and aims of the research activity. The goal of project PROACTIVE is to enhance societal CBRNe preparedness by increasing first responder's ability to effectively manage large, diverse groups of people. This will be accomplished by fostering common approaches between European safety and security Practitioners, in particular Law Enforcement Agencies (LEAs) and CBRNe First Responders. These are to be evaluated and validated against the needs and requirements of the civil society, especially considering vulnerable groups of citizens. These groups reflect the most important societal aspects, in line with the European Security Model (e.g. perception of security, possible side effects of technological solutions, gender- and age-related behaviour, and disabilities).

In that respect, the project PROACTIVE methodology is **consultation** with Practitioner-Stakeholders (e.g. Law Enforcement Agencies, CBRNe First Responders) and Citizens (through appropriate methods such as surveys, interviews and focus groups), followed by **detailed examination** of selected tools and procedures and the subsequent provision of **three field exercises** to evaluate their effectiveness via an effective, realistic, legal and ethical research platform.

This study is funded by the project no 832981 PROACTIVE (project funded by the European Commission).

Purpose of Study: [Insert brief paragraph.

		Please initial each box
1	I confirm that I have read and understand the information sheet for the above research activity. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences or penalty.	
3	I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data.	
4	I understand that this project has been reviewed by, and received ethics clearance through, the Project Ethics Officer of project PROACTIVE.	
5	I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	
6	I understand how this research will be written up and published.	
7	I understand how to raise a concern or make a complaint.	
8	[If applicable] I consent to being audio recorded	
9	[If applicable] I consent to being video recorded	
10	[If applicable] I consent to having my photo taken	
11	[If applicable] I understand how audio recordings / videos / photos will be used in research outputs [please delete as appropriate]	
12a	[if applicable] I agree to the use of direct quotes, attributed to my name, in research outputs **OR**	

12 b	[if applicable] I agree to the use of pseudonymised quotes in research outputs **OR**	
12 c	[if applicable] I agree to the use of anonymised quotes in research outputs **OR**	
12d	[if applicable] I do not wish to be directly quoted	
13	I agree to take part in the research activity	
Optional:	I agree for research data collected in this study to be given to researchers, including those working outside of the EU, to be used in other research studies. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified.	

Name of Participant	Date (dd/mm/yy)	Signature

Name of person taking consent

13. ANNEX 3 – PROACTIVE INFORMATION SHEET TEMPLATE

Optional statements are highlighted turquoise – delete if not applicable to your research (then delete all advisory text – highlighted yellow).

Please tailor the information sheet to the participant group (e.g. literacy level) and simplify it if needed. Note that you should aim for a reading age of 12 for an adult information sheet

[Research/Study Title]

PARTICIPANT INFORMATION SHEET

PROACTIVE PROJECT ETHICS OFFICER (PEO) Approval Reference: **[Insert]**

Background and aims of the research activity. The goal of project PROACTIVE is to enhance societal CBRNe (Chemical, Biological, Radiological, Nuclear and explosive) preparedness by increasing first responder's ability to effectively manage large, diverse groups of people. This will be accomplished by fostering common approaches between European safety and security Practitioners, in particular Law Enforcement Agencies (LEAs) and CBRNe First Responders. These are to be evaluated and validated against the needs and requirements of the civil society, especially considering vulnerable groups of citizens. These groups reflect the most important societal aspects, in line with the European Security Model (e.g. perception of security, possible side effects of technological solutions, gender- and age-related behaviour, and disabilities).

In that respect, the project PROACTIVE methodology is **consultation** with Practitioner-Stakeholders (e.g. Law Enforcement Agencies, CBRNe First Responders) and Citizens (through appropriate methods such as surveys, interviews and focus groups), followed by **detailed examination** of selected tools and procedures and the subsequent provision of **three field exercises** to evaluate their effectiveness via an effective, realistic, legal and ethical research platform.

This study is funded by the project no 832981 PROACTIVE (project funded by the European Commission)

Why is this research being conducted?

[Please state the background, purpose and aims of the research.

Why have I been invited to take part?	You have been invited because [e.g. include age range and inclusion/exclusion criteria]
Do I have to take part?	No. You can ask questions about the research before deciding whether or not to take part. If you do agree to take part, you may withdraw yourself from the study at any time, without giving a reason, [and without negative consequences – include if

	appropriate], by advising me/us of this decision. [If applicable - The deadline by which you can withdraw any information you have contributed to the research is [insert deadline before publication/submission of thesis]. [Please address what will happen to the data collected until the point of withdrawal.]
What will happen to me if I take part in the research?	[This section details what will be involved in your research from a participant's point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn. As a minimum you should include:] If you are happy to take part in the research, you will be interviewed/you will be asked to attend a single/multiple visit(s) [delete as appropriate] at [add anticipated location]. If applicable: When you arrive, I/we will talk you through the study procedures and give you the chance to ask any questions The interview/session should take approximately….. minutes/ hours. [For longer sessions: You will be offered regular breaks.] You can also ask to pause or stop the interview at any time If you are still happy to take part, I/we will ask you to sign a consent form. / OR give oral consent [only if applicable].
Will I be photographed / filmed	[If applicable:] With your consent, I/we would like to audio record you / video record you / take photographs of you [delete as appropriate] because…[give reasons why this is necessary here, e.g. for audio recording: so I/we can have an accurate record of your thoughts]

[Give details of any follow-up visits, with duration and frequencies].

Are there any potential risks in taking part?	The following risks are involved in taking part….[address any risks to participants, e.g. breach of confidentiality, safety issues etc.] To reduce any potential risks, [say what you will do, including that personal data will be pseudonymised or anonymised as appropriate].
Are there any benefits in taking part?	Either: The benefits of taking part are [say what the benefits are] OR There will be no direct or personal benefit to you from taking part in this research
Optional] Expenses and payments]	Either: You will receive [x amount/voucher/gift] for [participation/reasonable travel costs/meals]. Or: There will be no payment for taking part in this study

What happens to the data provided?	The information you provide during the study is the research data. Any research data from which you can be identified (please list here the personal data you are collecting from participants, e.g. name, date of birth, audio recording etc.) is known as personal data. [If applicable to the study: This includes more sensitive categories of personal data such as your racial or ethnic origin or data concerning your health] [Please list here the types of the sensitive data you are collecting]. Personal / sensitive data will be stored [insert location, security measures and how long the data collected will be stored for]. Other research data (including consent forms) will be stored for 5 years after the finish date of the Project PROACTIVE. [If applicable: Your personal data may be transferred to, and stored at, a destination outside the European Economic Area. Identifiable data will be removed whenever possible and any data transfer will be done securely and with a similar level of data protection as required under UK law. The [researcher and/or e.g. research team, collaborator / translator / transcriber/other authorised personnel…] will have access to the research data. Responsible members of the Project PROACTIVE may be given access to data for monitoring and/or audit of the research. [If applicable] I/We would like your permission to use direct quotes [and for your name to be attributed to these / anonymously / against a pseudonym] [please delete as appropriate] in any research outputs. [If applicable: I/We would like your permission to use anonymised data in future studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.]
Will the research be published?	The research may be published in [e.g. academic publications, websites].
Who has reviewed this study?	This study has been received ethics clearance through the Project Ethics Officer of Project PROACTIVE (Reference number: xxx).

Who do I contact if I have a concern about the study or I wish to complain?	If you have a concern about any aspect of this study, please contact [insert primary researcher name and email address] or PROACTIVE PEO: Irina Marsh irina.marsh@cbrneltd.com, and we will do our best to answer your query. I/we will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.
Data Protection	The [insert the name of the project partner] is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The [insert the name of the project partner] will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest.
Points of contact	If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact: [Insert Primary Researcher Name] [Insert Project Partner Name] [Insert Project Partner Address] Project Partner tel: [Insert Number] Project Partner email: [insert address]

Further Information and Contact Details

14. ANNEX 4 – PROACTIVE CONSENT FORM FOR USE OF IMAGES, VIDEO AND SOUND

CONSENT FORM

for use of images, video and sound recordings containing personal data

This is a consent form in relation to participation in……..[5] being undertaken for Project PROACTIVE (EU H2020 funded project number 832981). The organisers of this activity ask that you sign this Form to confirm your willingness to participate in it. You will be given a copy of this Form to keep. The information generated from the activity will be used as part of Project PROACTIVE (*Preparedness against CBRNE threats through common approaches between security practitioners and the vulnerable civil society)* an EU-funded project.

I give permission to Project PROACTIVE for photographs/video/sound recordings of me to be captured and used in printed and electronic media, including the internet, for research/dissemination purposes.

I understand that some images or recordings may be selected for preservation in the Project PROACTIVE archive (up to 5 years) and may be used for research, publication, education, lectures, broadcasting, display and exhibitions.

My participation in the activity is entirely voluntary and I understand that I am free to withdraw from further participation at any time during the period of data collection and engagement with the Research team without giving a reason and without my legal rights being affected in any way.

I consent to the processing of my personal information for this activity. I understand that such information will be treated in strict confidence and handled in accordance with the provisions of the General Data Protection Regulation (GDPR) Regulation (EU) 2016/679.

Signed……Name:……..……
……Date____/____/___

Project PROACTIVE's organiser of photography/recording activity statement: I - ……confirm that I have explained the nature, demands and foreseeable risks of participating in this activity to the volunteer.

Signed……Name:……

Date ____/____/___

[5] All highlighted text has to be adapted to the purpose and specific to the research

15. ANNEX 5 – PROACTIVE DATASET TEMPLATE

PROACTIVE Dataset	
Data identification	
Dataset description	What's in the dataset?
Data source & provenance	Where does the data come from? What steps has the data been through?
Data purposes and uses	What will the data be used for?
Partner roles	
Data owner & users	Who owns the dataset and holds the copyright (if applicable)?
Data collection	Which partner is in charge of collecting the data?
Data analysis	Which partner is in charge of analysing the data?
Data storage and deletion	Which partner is in charge of storing and deleting the data?
Related WP(s) and Task(s)	What are the relevant WP(s) and Task(s)?
Standards and methodology	
Metadata and documentation	What metadata (timestamps, storage, transfers…) and documentation will exist or be used?
Standards	What are the applicable ISO / technical / operational standards?
Access controls & security	What access controls and security measures will be implemented?
Anonymisation and encryption	Will the data be identifiable and how will it be encrypted or secured?
System information	What are the formats, software/hardware and file types that will be used?
Data availability and exploitation	
Data access policy	What is the access policy and dissemination strategy? What partners can have access to what data and under which conditions? What is the dissemination level of the data and the research based on it?
Data availability	Will the data be shared outside of the project? For what purposes can it be re-used? Are there embargoes or restrictions?
Personal data protection	Are the data personal data (relating to an identified or identifiable natural person)? Has consent been obtained or are other legal grounds applicable? Have the relevant legal

	principles been respected? Do the persons have control over their data?
Archiving and preservation	
Data storage and backups	How, how long and where will the data be stored and/or backed up?
Data deletion and archiving	When will data be deleted? What will happen after the project? Will research data be saved and archived for public access?