Driving Innovation in Crisis Management for ***E***uropean ***R***esilience

D91.3 - Ethical Procedures, Risks and Safeguards

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Document Information

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2.0	29 February 2016	ATOS	Quality check performed in this document

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List of Acronyms

Abbreviation / acronym	Description
CCTV	Closed Circuit Television (Surveillance Cameras)
Cf.	See
CM	Crisis management
CoE	Council of Europe
D	Deliverable
DoW	Description of Work
DP	Data Protection
DPA	Data Protection Authority
DRIVER	Driving Innovation in Crisis Management for European Resilience
ECHR	European Convention of Human Rights
ESAB	Ethical and Societal Advisory Board
EU	European Union
FD	Final Demo
FP7	Framework Programme 7
JE 1 & 2	Joint Experiments 1 & 2
M	Month
NESH	Norwegian National Committees for Research Ethics
PRIO	Peace Research Institute Oslo
REA	Research Executive Agency
SC 15	Special Clause 15 in the Ethical Guidelines of the FP7 agreements
SE 1 & 2	Subproject Experiments
SP	Subproject
TFEU	Treaty on the functioning of the European Union
UAV	Unmanned Aerial Vehicle
UDHR	Universal Declaration of Human Rights
UN	United Nations
WP	Workpackage

Project Description

DRIVER evaluates solutions in three key areas: civil society resilience, responder coordination as well as training and learning.

These solutions are evaluated using the DRIVER test-bed. Besides cost-effectiveness, DRIVER also considers societal impact and related regulatory frameworks and procedures. Evaluation results will be summarised in a roadmap for innovation in crisis management and societal resilience.

Finally, looking forward beyond the lifetime of the project, the benefits of DRIVER will materialize in enhanced crisis management practices, efficiency and through the DRIVER-promoted connection of existing networks.

DRIVER Step #1: Evaluation Framework

- Developing test-bed infrastructure and methodology to test and evaluate novel solutions, during the project and beyond. It provides guidelines on how to plan and perform experiments, as well as a framework for evaluation.
- Analysing regulatory frameworks and procedures relevant for the implementation of DRIVER-tested solutions including standardisation.
- Developing methodology for fostering societal values and avoiding negative side-effects to society as a whole from crisis management and societal resilience solutions.

DRIVER Step #2: Compiling and evaluating solutions

- Strengthening crisis communication and facilitating community engagement and self-organisation.
- Evaluating solutions for professional responders with a focus on improving the coordination of the response effort.
- Benefiting professionals across borders by sharing learning solutions, lessons learned and competencies.

DRIVER Step #3: Large scale experiments and demonstration

- Execution of large-scale experiments to integrate and evaluate crisis management solutions.
- Demonstrating improvements in enhanced crisis management practices and resilience through the DRIVER experiments.

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Executive Summary

This deliverable introduces the concept of research ethics and why ethical considerations are crucial in DRIVER, and sets out the basic guidelines to be followed in order to uphold the high ethical standards required for the project. These guidelines are e.g. those of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to the automatic processing of personal data (and especially the European Directive 95/46/EC39), national regulations by Data Protection Authorities relevant for the various DRIVER partners, and other regulations and guidelines (such as those of the Norwegian National Committee for Research Ethics in Science and Technology). Special attention is devoted to research ethics in the context of experiments, e.g. the importance and expected quality level of informed consent. For some of the partners in DRIVER, the issue of research ethics and Special Clause 15 is new [1: 13]. Other partners report that in DRIVER, new (and more complex) ethics issues have appeared that they have not experienced in other projects [1: 13]. Consequently, this deliverable fulfils two purposes: 1) it provides a basic introduction to research ethics that covers all the main aspects and areas[1], and 2) it discusses and addresses in more detail, some particular issues that are relevant for ensuring that DRIVER is conducted while adhering to the highest ethical standards[2]. More details regarding the latter (i.e. discussions on specific cases) can also be found in the first version of the Ethical Monitoring Report (D95.31), where partners were asked to share their experiences and challenges, and more detail regarding the former can be found in D95.21, D95.22, and D95.23, where PRIO provides practical guidance on how to obtain data protection approvals, which tasks will most likely need approval, and when these are due in time. Concretely, in addition to being a "report on ethical issues and challenges to the project's activities" (original DRIVER DoW, p. 179-180), and answering to the issues a)- h) as described there, this deliverable provides for the following ready-to-use applicable output for the DRIVER partners:

1. A template prepared by PRIO for Informed Consent Forms which can be adjusted and tailored to particular cases,
2. A template prepared by PRIO for Research Ethics Approval Applications which can be adjusted and tailored to particular cases,
3. A checklist for Research Ethics and data protection considerations,
4. A checklist for doing experiments,
5. A PowerPoint presentation with the most important principles and advice,
6. The basic material for the integration of research ethics into the SP2 methodology (in particular WP23).

[1] See also DRIVER D95.21 that described a plan for obtaining ethics approvals by PRIO throughout the project.
[2] See also DRIVER D95.31 Ethical Monitoring Report, which covers both all of the major ethics issues in part B4 of the DRIVER DoW, and also every particular issue that 25 DRIVER partners that were tasked to contribute to this report have reported as relevant in Year 1 of the project.

1 Introduction

There are many considerations that need to be taken into account when conducting research. It is important to respect laws and institutional and governmental policies (e.g. through obtaining authorizations in the preparation phase), but furthermore, the effectiveness and credibility of the research cannot be maintained without carefully weighed consideration and active implementation of ethical standards. Ethics should be an integral part of all stages of research, including planning, conducting and evaluation. These phases can be linked to the different phases of the crisis management cycle, where upholding explicitly and implicitly good ethical standards is relevant in the mitigation-, preparedness-, response- and recovery phase. Ethics in research encompasses both ensuring good scientific practice (i.e. *researcher* ethics), safeguarding individuals and even safeguarding society at large (i.e. *research* ethics) [2].

All research conducted within the scope of DRIVER is subject to ethical considerations, especially if the research activities potentially come into conflict with commonly recognized values. For example, if a focus group meant to represent the population does not actually account for the demographic variations in the population, the researcher(s) can be said to not respect societal values such as diversity. It is the responsibility of each consortium member and each task leader to ensure that research is conducted in an ethical fashion. This deliverable gives guidance about the kind of responsibility that each DRIVER member is expected to assume.

Research ethics concerns researchers, participants and bystanders. The DRIVER project involves the collection, processing and storage of data derived from individuals, both those internal and external to the project. At the very core of research ethics are rules and guidelines for the participation and protection of individuals partaking in the research activities, which refer to the standard European Commission research ethics. The principles of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to the automatic processing of personal data and especially the European Directive 95/46/EC39 for the protection of personal data must be strictly upheld at all levels when addressing ethics issues within DRIVER.

This deliverable aims at providing useful guidelines and recommendations for responsible research conducted in DRIVER. It will do so by presenting and clarifying the relevant ethical considerations to be taken into account for the research activities conducted in DRIVER, and special attention will be devoted to research ethics in the context of experiments, e.g. the importance and quality level of informed consent and ensuring the safety and wellbeing of researchers, participants and bystanders.

The wish for more checklist- style recommendations for research ethics was expressed in both bilateral communications with partners, and by several partners through the 25 questionnaires that formed part of D95.31 [1:22]. For this reason, and because research ethics is something new for

some of the DRIVER partners [1:13], we have included an easy-to-read recommendation list for research ethics in the end of the deliverable. We have also included a recommendation list for the DRIVER experiments in Chapter 11, which goes beyond the concept of data protection, and also gives more general practical guidance on how to take care of ethics when conducting experiments. This list demonstrates how such considerations can be directly implemented into the experiments e.g. through the D23.11, the Experimentation Design Manual[3]. However, although research ethics can be summarized in the format of lists, it is important to acknowledge that research ethics is a complex and dynamic concept that needs to be scrutinized in the individual cases. Thus, while providing an introduction to research ethics, the deliverable also addresses more complex and subtle issues concerning research ethics which have been added since the original submission.

The set-up for the remainder of this deliverable is as follows. The rest of Chapter 1 explains the relation of this deliverable to the other deliverables relating to research ethics, e.g. D95.21 that already covers the very basics of research ethics in the project. Chapter 2 gives an explanation of the impact of the Year 1 review on this deliverable, and explains how this resubmission addresses the reviewer's comments. Chapter 3 introduces the very concept and foundation for research ethics, and discusses in some detail key terminology in order to reveal partly the complexity of research ethics. Chapter 4 explains and addresses the most important data protection rights and challenges. This includes the concepts of personal data and sensitive data, through the notion of the "data subject". Chapter 5 applies the procedures needed to uphold the data protection rights explained in Chapter 4. This includes the approvals set out by SC15, and the steps needed to take in order to obtain these approvals. Chapter 6 details the DRIVER experiments, and the sources of data and approvals needed in these. In Chapter 7, we go into detail about the recruitment of participants in research, i.e. what it implies to include participants and the importance of informed consent. Chapter 8 describes key security measures for the protection against misappropriation of data and for protection of privacy through limiting intrusion. Chapter 9 describes some risks and challenges to ethical research by giving some example scenarios. Chapter 10 summarizes the most important recommendations from this deliverable in a list of general recommendations for ethical research, and Chapter 11 summarizes and lists general recommendations for the DRIVER experiments. Chapter 12 concludes. The annex contains templates for Informed Consent Forms and Research Ethics Approval Applications. In addition, a PowerPoint presentation with a summary of the most important principles and advice will be circulated with the deliverable.

[3] The deliverable was rejected in Year 1 and will be resubmitted. Here, we offer a much more detailed and thorough list for integration into the experimentation methodology than we did in the first submission of D23.11.

1.1 The Relation to D95.21, T95.22, the ESAB & D95.31

This deliverable is one of several channels, activities and documents that address ethics issues in DRIVER. Firstly, it draws on input from, and serves as a detailed supplement to, D95.21 (New: D14.21), where the plan for those tasks which require approval and how to get the approval was already provided in M2 of the project. Although D95.21 (New: D14.21),, according to the DoW, is merely "A detailed planning of ethical approvals required per task/activity" (provided by PRIO in table-form), the opportunity was seized to clarify and state the most relevant ethical principles and procedures already in D95.21 (New: D14.21), since data collection started already from M1, and this could not wait until the first version of D91.3 (New: 14.3) in M6. The approvals that were needed according to the plan in D95.21 (New: D14.21), are then collected through T95.2 (New: T14.2).

In the annual Ethical Monitoring Reports (first one ready in M12, April 2015), key ethical issues in DRIVER are documented and addressed. The purpose of the Ethical Monitoring Report is both to clarify some particularly important points regarding research ethics, but also to update and specify previously given guidelines. These deliverables also take up the most pressing or challenging ethics issues as seen by PRIO and experienced by the DRIVER partners. The input to the report is (and will most likely also in the future) mainly derived from five different sources: 1) Ethical Monitoring Questionnaires filled out by 25 DRIVER partners, 2) the Ethical and Societal Advisory Board which held its first meeting in December 2014, 3) interaction during and after the DRIVER meeting week in Ispra February 2015, in particular the presentation on research ethics given by PRIO during the General Assembly, 4) issues of ethical concerns which became apparent to PRIO as SP9 leader (in particular as leader of WP91 (New: WP14) and WP95 (New: WP14)) and 5) the information repeats and refines some core points from previous deliverables within SP9. The purpose of describing these five sources here is to demonstrate that mechanisms and channels exist to ensure the uptake of potential ethics issues that might appear. Since PRIO (the old WP95/T91.3, now WP14/ T14.3) cannot participate to every single experiment where potential challenges might occur, the Ethical Monitoring Reports works as a safeguard where such issues can be raised.

In sum, in D95.21 (New: D14.21), we indicate which tasks need approval and when, in D91.3 the procedures, risk and safeguards for getting these approvals and for maintaining high ethical standards are given, and in T95.1, these approvals are collected and stored per task by PRIO. In addition, through the Ethical Monitoring Reports in T95.3 (New: T14.4), ethics issues and principles that pose challenges or are especially important to the project are documented and addressed. Finally, particular ethical challenges are discussed with the Ethical and Societal Advisory Board in annual meetings, and these discussions are documented through T95.1 (New: T14.1).

1.2 The Scope and Limitations of T91.3

In the previous chapter we described the relation between this deliverable and other deliverables and tasks dealing with research ethics (now all the ethical tasks are part of SP1/ WP14). In the following, we describe further the scope of this deliverable, and what is does and doesn't do. In short, this deliverable explores the concept of research ethics, and sensitizes the consortium towards useful and applicable ethics.

What this deliverable does:

- Provide guidelines and describe the basics of research ethics in order to introduce this to those partners that are not familiar with research ethics.
- Describe and give guidance on data protection procedures, and the potential ethics approvals needed for DRIVER research activities.
- Describe and give guidance on the inclusion of participants in research.
- Provide for more in-depth discussions about the subtle nuances of research ethics and the conceptualization of research ethics, and introduces and describes some key terminology relevant for understanding these issues.
- Describe and give guidance on other ethical considerations to mitigate risks and safeguard key ethical principles for conducting research.
- Point to what different kinds of experiments that is likely to take place within DRIVER. The main goal is to do this exercise of categorization in order to determine/ sensitize the consortium towards whether there are experiments planned within DRIVER that need *additional* approvals that go beyond the classic ethical approvals (in terms of data protection). However, this can only be determined once the planning of the experiments is finalized, and this is a continuous effort throughout the project.
- Give list of recommendations for general research ethics, and ethics for the DRIVER experiments.

What this deliverables does not:

- Provide guidelines for the general approvals (e.g. UAV flight allowance) and insurances (from law enforcement, official agencies etc.) needed to conduct experiments. Such approvals and considerations are the legal responsibility of the individual experiment leader/ task leader, and not of PRIO.
- Give direct guidance and advice on very specific cases. This happens through T14.2 (Old: T95.2) where bilateral ethical guidance can be given on request by the partners needing it, and through the T14.4 (Old: T95.3), the Ethical Monitoring Reports, which was submitted in first version in M12, and will be submitted in second version in M24. Here, the partners can raise specific questions and address more general issues on research ethics.
- Describe in detail the input and feedback that the Ethical and Societal Advisory Board have had in SP9 (New: WP14/ T14.4). This can be found in the deliverables in T95.3 (New: T14.1) and in the deliverables in T95.1 (New: T14.1).
- Speak to every single experiment that happens in DRIVER.

2 Impact of the Year 1 Review on this deliverable

As a result of the Year 1 review of DRIVER, some issues need to be addressed. In short, the following paragraphs will explain and give an overview of 1) which remarks the reviewers had for D91.3 (submitted in M6) and 2) how PRIO has answered to these, by implemented requested amendments and changes. Below, we answer directly to these specific comments from the reviewers of the Year 1 review in the DRIVER Consolidated Review report [3: 39], and we also explain where in this deliverable these changes and amendments can be found. The remainder of this chapter is a summary of the changes resulting from the review, which have been implemented throughout the rest of the deliverable.

The remarks from the reviewers are divided into five sections. The remarks to the original submission of D91.3 were as follows:

1. **TOO GENERAL AND STRAIGHTFORWARD**

   (…) all these [ethical] issues are handled in an exceedingly general level specially compared to the length of the project."

   a. "For example, the deliverable starts with Section 2.3 which is a straightforward discussion of obvious practices and ethical considerations - and this could be a deeper and broader discussion e.g. discussing what is really meant by the terms: data protection, transparency and accountability."

Providing an introduction to research ethics is a "balancing- act", where a careful consideration of the level of complexity with which the issues are communicated to the consortium is needed. From bilateral guidance and follow-up (through emails, phone calls, face-to-face conversations) with partners that have requested assistance in terms of research ethics, and from the feedback that was provided by the 25 partners that gave their input to the first Ethical Monitoring report, it became clear that a basic introduction to research ethics in a clear and easy-to-read manner is needed for many partners in DRIVER.

Through D95.31 it became clear to PRIO that there are partners in DRIVER that have no experience with research ethics, and who need this very basic introduction. At the same time, the large majority of the respondents to this questionnaire reported that no new ethics issues which they have not yet encountered have appeared in DRIVER, implying that they have handled similar issues before. To balance these two needs is a challenge, but the reason that this deliverable is written in an introductory style is also because there are in fact differences in research ethics (e.g. for the use of UAV's, and the requirements for storage of sensitive data from different Data Protection Authorities)

although the European regulations for Data Protection are largely harmonized across the 13 DRIVER partners countries. For this reason, a general overarching introduction to research ethics is given in this deliverable that will be relevant for *every* partner in DRIVER that conducts research activities.

However, because of regulatory differences between countries, advancement and developments in the DRIVER experiments (JE1 & JE2), and the general progress of the DRIVER activities, we also acknowledge that there is also an increasing need to address and assist partners in more concrete and particular ethics issues.

To answer to this "balancing- act", this resubmitted deliverable will on the one side: 1) expand and detail the general introductory guidelines for responsible research ethics (mainly Chapter 4 & 5), and on the other side 2) go more into depth about the underlying assumptions and definitions related to such concepts as data protection, transparency and accountability (Chapter 3). It will also more clearly and explicitly link and refer to the other deliverables produced within the old SP9, where some of the issues that the reviewers requested are addressed. This deliverable is then both wider and deeper, since new chapters have been added, and old chapters have been expanded.

2. LACK OF AUTHORITATIVE SOURCES

"There is very little reference in this deliverable to authoritative sources that have been consulted on these complex and dynamic ethical terms – suggesting that little in-depth thought has been devoted to uncovering the complexities and tensions in research ethics."

The revised version of this deliverables includes more sources of reference. This includes policy documents, academic literature, legal texts and legislations, EU law, national guidelines (e.g. NESH in Norway), as well as some input and references from other already submitted deliverables of relevance. In addition, a member of the DRIVER Ethical and Societal Advisory Board has reviewed the deliverable.

3. SIMPLICITY AND LACK OF SUBTLENESS

"The section on experiments (beginning of 3.2) seems less than useful and treats the issues in a simplistic manner. Section 5 is good in terms of the transparency with which it has been developed in the document. However, ethics is a very complex issue, and much of document is relatively simplistic and does not fully uncover the subtle issues."

a. "For example, a person simply signing an approval form because they do not want to disclose that they cannot comprehend its contents (so they don't know what they are signing)".

In response to this issue that overlaps with remark number 1 above, we have added a chapter where we introduce more fundamentally the concept and foundation of research ethics and why it is important (Chapter 3). Furthermore, we present some key terminology and concepts, and discuss the question of research ethics as a question of methodology (Chapter 3.2 & Chapter 3.3). We also give

examples of ethical dilemmas in research, to further illustrate subtle issues of research ethics (Chapter 9). These are meant to inspire critical thinking about research ethics, and illustrate that it is not always possible to make ethical guidelines that suit every situation, because these depend on context etc. However, throughout the document, effort has been dedicated to detail and circumstantiate ethics issues where relevant. It should also be noted that the level of complexity in the ethical guidance we can give for the conduction of experiments completely relies on the level of detail in the planning of the experiments. As the Joint Experiments (JE1 & JE2) are still being planned at this point in time (the delivery of their design is tied to Milestone 2, and is planned delivered in M21, after submission of this deliverable), it is only possible to give general- yet applicable- guidance on research ethics with regards to them. However, this deliverable still provides useful guidance for the experiments (both single experiments and the JE's)[4]. It does so especially by e.g. giving clear instructions on whether the task leader needs approvals, how to get approvals, and what might trigger other kinds of approvals than data protection approvals.

4. PROCESS FOR ETHICAL CHALLENGES

"Processes for dealing with ethical challenges are not discussed e.g. an ethics board or adjudicator."

As an answer to this, this deliverable has been updated with a more clear description of the link between T91.3 and the rest of the tasks that involve research ethics, for example the Ethical and Societal Advisory Board. The minutes of the two meetings where the ESAB was consulted and ethical challenges were discussed with the Board, can be found in D95.11 and D95.12. In addition, as a result of the questionnaires distributed as part of the first D95.31, 14 out of 25 partners reports that they have already started engaging with their relevant Data Protection Authorities for guidance. This implies that these partners, until M12, were aware of how to start/continue/ follow up the process of getting approvals or resolving potential challenges. Out of the partners that reports that they haven't been in contact with DPA's or ethics committees, the majority state that it is because it has been decided that approval is not needed. The general process for obtaining ethics approval (i.e. also who to contact in case of challenges) is described in D95.21 (page 12) and in D95.31 (page 14). A detailed description of the ethical challenges that the partners report to have experienced in Year 1, as well as the main ethical challenges as far as SP9 sees them, are further described in D95.31[5]. Finally, the efforts allocated to T91.3 does not allow for a mapping of the procedure for dealing with Data Protection Authorities and Ethics Boards in each of the 13 DRIVER countries. PRIO rather gives a basic and general introduction to research ethics, draw up some potential challenges on a more

[4] In addition, the part of the old SP9 that deals with research ethics is not completely detached from the part of the old SP9 that deals with Societal Impact Assessments. A major effort is currently taking place between SP8 (basically a merge of SP9 & SP8) and SP2, SP3, SP4, SP5, SP6 (it is in SP6 that the JE's 1 & 2 run in parallel), in order to align the definitions and categorizations of the DRIVER functions, on which the assessments that takes place within SP8 is built upon. This alignment (implemented in first version in deliverables in WP84 that PRIO lead) will eventually make the task of ensuring that the ethical standards in research ethics is high easier, because the definitions of the activities, solutions and tasks that the JE's will contain, will be easier understood by the DRIVER partners.

[5] E.g. Chapter 5 presents the role and activity of the DRIVER Ethical and Societal Advisory Board (ESAB) thus far, and some issues suggested by the DRIVER partners to be brought to the board.

general level, and then follows up with each partner that come across ethical challenges as the challenges appear (through both the ESAB and T91.3).

5. UNCLEAR PURPOSE OF THE DELIVERABLE

"(…) its purpose as a deliverable is unclear."

The reviewers found the purpose of this deliverable to be unclear. In response to this, we have strengthened the structure of the deliverable to more clearly follow the structure as indicated in the original DRIVER DoW[6]. The deliverable answers all points a) – h) (here listed 1-7) indicated in the DoW (see below). At the same time, the review report reads: "This deliverable is a report on ethical issues and challenges to the project's activities. The deliverable includes information on ethical issues as well as some risks and recommendations related to the DRIVER project" [3: 39]. PRIO considers this description to still be valid for describing the purpose of the deliverable, but have made an effort to explicitly answer to the structure in the task description in the DoW, in order to make the purpose more clear.

Partly overlapping with the reviewers comments mentioned in the five sections above, what the deliverable should contain as per DoW (here: point 1- 7), and where in this deliverable the content can be found (a/b), is described below:

1. "Required approvals/notifications by the competent local/national Ethics Committees/authorities as set out by Special Clause 15".
    a. The general (and more detailed) procedures are described in Chapters 4 and 5 in this deliverable, but additional applied and practical guide is also given with explicit linkage to the actual tasks and activities that require approval in D95.22 and D95.21. Particular challenges linked to these processes are described in the first (and later, in the following) Ethical Monitoring Report in T95.3.

2. "Information on sources of experimental data".
    a. The DRIVER experiments are described in Chapter 6, where the main sources of data collection in the experiments conducted within DRIVER are described. Although the DRIVER experiments have moved further since the original submission of this deliverable, the Joint Experiments are still under planning. However, it is *still likely that only DPA approvals will be need***.** This is because no medical research is foreseen, which the ESAB described as the only likely context that would trigger other kinds of ethical approvals, such as those of an ethics board dealing with medical research [7:8] [1:14].

[6] Although the project as a whole is currently undergoing heavy restructuring, the re-writing of the DoW in the following weeks should not change much in the description of this deliverable. The set-up of the research ethics component (which after the restructuring is moved to SP1), will not change much.

3. "Recruitment of participants in research activities".
    a. This is described in Chapter 7. Here, the concept of informed consent is the most relevant. The large majority of the respondents to D95.31 reported that they had used the template that is annexed to this deliverable, and that they have not encountered any problems with getting real and active informed consent [1: 19ff]. Chapter 7.2 gives more detail in terms of EU law regulating the concept of informed consent.

4. "Clarification of procedures to be used in order to ensure privacy, confidentiality in data collection, storage, protection, retention and destruction and confirmation of data".
    a. These are basically the general procedures and rights in terms of data protection. These procedures are described in Chapter 5 of this deliverable, and a broader discussion of more fundamental issues can be found in Chapter 3.

5. "Security measures that will be implemented to prevent improper use, improper data disclosure scenarios and 'mission creep'".
    a. In Chapter 8, this deliverable gives an overview of key security measures for the protection against misappropriation of data and for protection of privacy through limiting intrusion. However, there are indeed overlaps between security measures and the general principles for data protection that is described under the previous point (number 4).

6. "Justification and limitations of measures that enable tracking of location or observation of people that is planned to take place in the frame of the proposed research".
    a. This is incorporated in the general guidelines for data protection, but in Chapter 8 we give an introduction to the most common and widely used measures to mitigate the risks that measures such as geo-tracking or observing tools or solutions can entail. In addition, we included a dedicated chapter on "UAV's and data protection" in D95.31, where the issue of location tracking might also be of relevance.

7. "Measures that need to be introduced so as to mitigate risks associated with the potential use of research findings to violate the privacy of citizens".
    a. This is very much linked to general data protection rights and challenges described in Chapter 4, as well as data protection procedures as described in Chapter 5. In addition, Chapter 8 in describes protection of privacy through limiting intrusion.

As shown, the seven points described above are incorporated into the different chapters in the rest of this deliverable. In the next chapter we will be introducing a more conceptual discussion about terminology and the importance and fundamental nature of research ethics.

3 Introduction to the Concept and Foundation of Research Ethics

In this chapter we will reflect upon the more overarching and general concepts that are relevant for understanding the foundation of research ethics. With explicit reference to this deliverable, the General Assembly took part in a presentation on research ethics held by SP9- leader during the DRIVER meeting week in Ispra, Italy February 2015. This workshop aimed at introducing the concept of research ethics and its basic conditions and considerations to the consortium. The following chapter describes the importance of the concept research ethics, as well as some key terminology.

3.1 Why Research Ethics?

There are several entry points into research ethics. For example one can see research ethics as the practical and formal requirements[7] that are in place in various forms to protect the researcher and the participants in the research. In addition, research ethics can be seen as more general ethical principles linked to maintaining or strengthening societal values, such as equality and non-discrimination. However, there is also more philosophical and fundamental sides to the ethical concepts and considerations of research[8]. It is obvious that individuals apply ethical concepts- such as the concept of goodness, duty, obligation, virtue and justice, to certain states of affaires, actions, properties of actions and personal characteristics [8:10]. A researcher can be concerned with several aspects of these concepts, for example: What do they contain? What do they mean? How do they materialize in the carrying out of the research? To what do the concepts apply? Where did they come from? How did it come about that we started using them? Ethical concepts are, or purport to be, normative [5], because they make claims on us by commanding, obliging or recommending us to do certain things. Within this normativity also lies the potential negative and positive societal impact of the DRIVER activities and results, because an individual can choose to take account of ethical principles or concepts, or to not do so, and the effect this can have can either be positive or negative depending on context etc. For example, acknowledging that it is important to respect human dignity in the research activity is not the same as carrying out the research in a way that (actively or passively) enforce or respect this value.

To put it simply, the approach to research ethics in DRIVER can be seen in two ways. On the one hand, research ethics is about the need for formal compliance. Framed within the DRIVER project,

[7] For example, ethics approval is important because in some cases, the researcher is not covered by the institutions insurance unless ethics approval has been obtained in advance of the activity. In such an example, having an ethics approval in place beforehand can eliminate the risk of the researcher being made personally liable in case of an unforeseen claim.

[8] See also D95.31 Chapter 3.1 (Chapters 3.1.1 & 3.1.2) where the role of human subjects in research is discussed and how the fact that a human being is both a biological, emotional and spiritual being can come into play (page 18), and furthermore, an introduction to the basic phycology of crisis exercises (page 19) and the fundamental importance of protecting vulnerable groups (page 19). These chapter also illustrates why research ethics matter on a fundamental level.

these kinds of ethical concerns are mainly conceptualized and materialized in formal requirements and legal obligations, e.g. through the application of data protection regulations, and other ethical considerations to protect the privacy of the individual participant in the research or to protect them from other kinds of harm. Closely linked to this, on the other hand, high ethical standards in research is about contributing to the development of a culture of ethics. Fundamentally, as the result of a long tradition of the development of research ethics, DRIVER adheres to such prerequisites such as those stating that research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. This is important because the rationale behind these ethical rules and principles includes certain safeguards that, if not upheld, would put the very foundation of research at risk. Safe and sound research activities contribute to accountable and legitimate research outputs. Many research activities within DRIVER will be subject to approvals regulated by Special Clause 15, such as most interviews and experiments (e.g. experimental tests of crisis management solutions, table-top exercises, and workshop-like activities). Within FP7 projects, Special Clause 15 regulates the collection and processing of personal data, which means that any research involving personal data is subject to approval by the data protection authorities (DPAs) of the country in which the data is collected [6] (cf. Annex 2). D95.21 already informs the consortium about the different points in time when the research activity subject to such approvals take place (see for example D95.21 Chapter 5).

Aim for high ethical standards. This is important because such standards generate from principles and safeguards that if not upheld, would put the very foundation of research at risk. Safe and sound research activities contribute to accountable and legitimate research outputs.

3.2 Key Terminology & the Conceptualization of Research Ethics

In this chapter we will provide an overview of the key concepts that have direct or indirect impact on research ethics, and we will also give an example of where/ how the concept is relevant within DRIVER. Partly, the following definitions can also be found in D84.11 “Societal Impact Assessment Framework” (which will be updated and revised towards the end of the project), where the following defined concepts form part of the criteria system that is used to assess the societal impact of the DRIVER Crisis Management functions [10: 37, 43, 45]. By linking requirements for ethical research with the criteria that we have developed for assessing the societal impact of the DRIVER functions [10:33], we emphasize that good or bad research ethics can indeed have an impact on society, and we also broaden the discussion of why these ethical requirements are important. Within this also lies the acknowledgement of the fact that it is not necessarily enough to only oversee the contractual and legal requirements for research ethics, but it can also be seen as affecting the society at large, and thus, we can take steps to ensure that this impact is regulated, and that the best solutions are

selected. In this way, by taking into account societal values and insecurities, we can push the boundaries for research ethics, and make an example of "best-practise research ethics" in DRIVER. However, it can be a challenge to translate such considerations (considerations with regards to e.g. fear, societal cohesion, the principle of transparency etc.) into actionable recommendations.

In the next paragraphs, we present a more practical and applicable brief explanation of the terms and concepts of privacy and data protection, as well as other "supporting" terms and concepts relevant for understanding the depth and width of research ethics, and how these can have an impact on society. In terms of the relationship between the ethics of CM measures and the ethics of research, in the context of this deliverable, it should be underlined that the focus in this deliverable is research ethics. However, to some extent this is overlapping/ transferrable to the CM measures that are potentially implemented as a result of the research. The following paragraphs are partly quoted from D84.11, where they are meant to illustrate potential societal impacts of CM measures. Although the definitions were originally aimed at describing the concepts as criteria for societal impact, they are also included here, as a way of framing research ethics within a larger societal context and to answer to the reviewers request for a broader discussion of what such terms may encompass and also their request for uncovering the more subtle and ambiguous issues of research ethics. Please note that these definitions does not aim to cover everything that e.g. "transparency" can mean, but are here meant to shed light on their relevance for understanding the wider concept of research ethics.

Privacy & Data Protection

The purpose of data protection rules is to ensure privacy, ensure confidentiality in data collection, and data processing/handling, and to regulate storage, protection, retention and destruction and confirmation of data. The guidance and recommendations in this deliverable basically relate to research conducted in SPs 3-5 (single experiments and the JE's), and also some aspects that will be relevant in SP6 (JE1, JE2 and FD) and SP2 (as part of the experimentation methodology). The most relevant and likely considerations that need to be taken and approvals that will be needed, relate to the protection of privacy and data protection.

In D84.11 [7], for the purpose of making Societal Impact Assessments, we define and conceptualize "Privacy & Data Protection" in the following way:

The content and concept of privacy is contested. It mainly refers to the right to seclusion and to the right to create an intimate sphere. Article 7 of the European Charter for Fundamental Rights [8] protects the right to privacy as the right for private and family life. But privacy is no longer "the right to be let alone" only [9]. It has become a concept, a regime, a set of policy instruments and a way to frame civil society activism [10]. A working definition is "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others" [11]. As such, it is closely related to the protection of personal data (Article 8). Protection also means that data has to be processed fairly, with the consent of the concerned person, who also has the right to access these data. This right was framed as the right to

"informational self-determination" [12], which is quite similar to the right to privacy. Both, privacy and data protection no longer relate to individuals only but is something that potentially affects society as a whole [13]. The implementation of privacy friendly CM measures would mean to implement measures that respect the right of the individual to have a private life.

> *Example: A breach of privacy happens if informed consent is not obtained before the collection of personal data from individuals included in e.g. focus groups or interviews, thus guidelines and regulations for respecting privacy should be in place before the start of the activity. CM measures that respect, and even advance best practice solutions in the area, have the opportunity to foster trust in the population and improve the (political) reputation of the CM actor(s). This opportunity is closely linked also to the notion of transparency and legality.*

Accountability

There are different ways of defining accountability. As mentioned above, the most relevant and likely considerations for research ethics that need to be taken in DRIVER, relate to the protection of privacy and data protection. As part of the principle of fair data processing, which seeks to govern the relationship between the data controller and the individual whose data is being collected, accountability requires the active implementation of measures by data controllers to promote and safeguard data protection in their processing activities [17: 78]. The organization for Economic Co-operation and Development (OECD) adopted privacy guidelines in 2013 that highlighted that data controllers have an important role in making data protection work in practice [17:78]. Furthermore, according to Article 29 Working party's opinion, the very essence of accountability is the obligation of the data controller to: 1) implement measures that, under normal circumstances, guarantee that data protection rules are adhered to during the data processing, and 2) have documentation ready in order to prove both vis-à-vis data subjects (the individuals from whom the data is collected) and to other authorities, that security measures have been taken in order to adhere to data protection rules [17:79].

However, accountability can also be understood in broader terms, and this approach can be found in D84.11, where, for the purpose of making Societal Impact Assessments, we define and conceptualize "accountability" in the following way [10:33]:

Accountability is the obligation of an individual or organization to account for its activities, accept responsibility for them, and to disclose the results in a transparent manner [15]. As a core value of good governance, public accountability ensures that actions and decisions taken by public officials are subject to oversight in order to guarantee that these initiatives meet their stated objectives and respond to the needs of the community they are meant to be benefiting [16]. Responsible and open communication is a central part of accountability for CM.

> *Example: If CM organizations and actors, during a crisis, implement measures without acting accountable with regards to their use, this can have negative side-effects. E.g. because communication during the crisis was not transparent, potential mishaps is hard to learn from*

in the aftermath of the crisis[9]*. It is thus crucial to determine accountabilities beforehand as a part of planning measures and tools, in order to reach the most positive societal effects.*

Transparency

Transparency can refer to a number of issues in crisis management, for example transparency relating to evacuation decisions and communication, and it is also relevant in relation to data processing. As part of the principle of fair data processing, which seeks to govern the relationship between the data controller and the individual whose data is being collected, the concept of transparency is established as an obligation for the data controller to keep the "data subjects" informed about what happens to the data that is collected on them. In other words, fair processing in this context means transparency of processing, especially vis-à-vis the data subjects [17:76], who has the right to learn how their data is being processed in an easily understandable and accessible manner by the data controller.

In D84.11, for the purpose of making Societal Impact Assessments, we define "Transparency" in the following way [7]:

Transparency means information disclosure, clarity and accuracy to enhance "the perceived quality of intentionally shared information from a sender" [17]. Transparency is then also to communicate about and make those kinds of actions visible that cannot be perceived by the crisis population directly, but that may nonetheless have consequences for their rights, actions and reactions. An open society is often characterized by a high level of transparency, meaning e.g. public discussions and debates are conducted in a way that allows for the public to follow them.

Example: If a CM measure foresees the implementation of technologies that may collect personal data, transparent communication explains publicly and in an accessible manner what kind of data that would include, what it does not include, which purpose it serves and how it is going to be stored, processed, shared, and deleted. If these aspects are clearly and transparently communicated before, during or even after emergencies, the societal acceptance of such measures may be higher because they are more predictable to relate to for the population.

Suitability, Necessity & Proportionality

In the context of research, the principle of proportionality refers to maintaining a balance between risks, burdens and potential benefits. Although these three concepts are valid in almost all aspects of research, in this paragraph they are linked most directly to issues of data protection. For example it is important to balance the need for collecting sensitive data, and how proportional the data collection

[9] There are examples that demonstrate the effect of transparent communication during a crisis, while following a transparent policy. See for example Perko, T., Turcanu, C. and Carlè, B. 2012, *Media Reporting of Nuclear Emergencies: The Effects of Transparent Communication in a Minor Nuclear Event* in Journal of Contingencies and criris Management. Volume 20, Issue 1, pages 52–63, March 2012

is to the case, with the risk for the data being used to identify the so-called data subjects.[10] The suitability, necessity and proportionality of data collection are addressed for example in the Council of Europe Convention 108, which concerns the *quality* of the data, and states that the data must be adequate, relevant, accurate, and proportional to the case. In addition, in Article 52 (1) of the Charter [8] it is stated that limitations may be imposed on the exercise of data protection rights (such as those set forth in Articles 7 and 8 of the Charter), as long as these limitations are provided for by law. In addition, the limitations must respect the core of those rights and freedoms, and be subject to the principle of proportionality, (meaning i.e. that they are necessary) and that they genuinely meet the objectives of the general interest recognised by the European Union or the need to protect the rights and freedoms of others[11] [17:21].

In D84.11, for the purpose of making Societal Impact Assessments, we define "Suitability, Necessity & Proportionality" in the following way [7]:

The so-called «proportionality test» is an instrument in EU law [18] to determine fairness and justice. It examines the suitability of a measure/tool in terms of its suitability, asking whether the appropriate means are being used to pursue the given objective. In a second step, the test examines the necessity of a measure/tool, asking whether there is an alternative measure that is less restrictive than the measure in question and that is equally effective in achieving the pursued objective [19]. Finally, the «proportionality test» examines the proportionality in strict sense, namely whether the effects of the measure "are disproportionate or excessive in relation to the interests affected. At this stage the true weighing and balancing takes place" [22:1].

> *Example[12]: Airborne sensors in unmanned aerial vehicles (UAVs) can be a suitable means to get an overview of an emergency situation. Alternative measures, for example manned helicopters (for non-automated data collection), do exist to fulfil this task as well. Helicopters may, however, be more expensive, so there is potentially a financial necessity to use airborne sensors; or sensors might have an added value as compared to human surveillance. The key question is then whether an airborne sensor, by collecting vast amounts of data that is not relevant for the situational analysis, is proportional to the objective in the narrow sense. In other words, both for doing research and in an actual crisis situation, is the data collection that the UAV does, proportional to the case? Are the situations when the use may not be easily justified? Asking such questions can help illustrate e.g. the potential burden to participants (those being potentially unnecessarily surveilled.*

The description above of some key concepts used to situate/ contextualize the complexity of research ethics within DRIVER, also describe key criteria used to assess the societal impact of the project's activities. By linking research ethics to societal impact, we demonstrate that research ethics

[10] For a closer discussion and analysis of the potential risk for identifying participants that have been anonymized for the purpose of a study, see for example Sweeney L, Abu A, and Winn J. 2013, *Identifying Participants in the Personal Genome Project by Name*. Harvard University. Data Privacy Lab. White Paper 1021-1. April 24, 2013.

[11] See, for example, CJEU, Joined cases C-92/09 and C-93/09, Volker and Markus Schecke GbR and Hartmut Eifert v. Land Hessen, 9 November 2010, para. 50.

can indeed have a significant societal impact. In the next chapter, we will speak about research ethics in a more *applied* sense, as fundamentally embedded in research methodology, and all phases of the research.

> Reflecting upon terms such as *transparency*, and *accountability,* which govern the relationship between the researcher and the individual whose data is being collected, can create a better understanding of the concept of research ethics.

3.3 Research Ethics as a Question of Methodology

Research ethics refer to questions of methodology. The DRIVER experiments can include a range of activities, meaning anything from interview and workshop sessions to acting out a scenario[13]. A thorough planning of experiments, for example when designing scenarios or questionnaires, means to design them as realistic and as targeted as possible in order to be able to reach the goal of experiments, reduce complexity and reflect upon the potential shortcomings of the selected method. It is thus important to contemplate on how the output of an experiment is limited by the selected methodology, the selected population and the specific conditions of the experiment. In addition to that, what you observe when conducting an experiment is highly influenced by what you expect to find or even what your employer expects you to find (principal-agent-problem [20]). It is important to reflect on these preconditions when reporting and discussing the results of an experiment. Another issue has to do with the concept of validity. Experiments are rarely reproduced, because they might be very expensive, or simply because the interest in the research has worn off as it has been done before. The ideal, following good research ethics, would be to repeat important experiments (in the more traditional sense) in order to detect potential skews or flaws in the design of the research or in the findings of the researcher. This can be difficult in terms of resources available to do so, but testing tools and procedures throughout DRIVER (first in the SE's, then the JE's and finally in the FD) thus increases the validity of the research results.

For ensuring a sound research methodology, the Norwegian National Committees for Research Ethics (NESH) has raised some "red flags" that must be taken into account when conducting experiments, because they might indicate that additional follow-up may (either with an ethics committee, or internally in the organization in order to re-work the methodology) be required. Pay attention to whether your research carries the following traits:

[13] In this section, the focus in on the overall concept of experiments, but for a description of the different kinds of DRIVER experiments, and the particular considerations and requirements for ethical research in this regard, see chapter 6 in this deliverable.

- The research could have a questionable or immoral starting point and / or ambition.
- The research could infringe upon the integrity of the research subjects.
- The results of the research could be too general or rooted in too far-reaching claims about reality.
- Research could be influenced by “wishful thinking”.
- The researcher needs to be aware of the limitations of the research results.

Take into account in the analysis of your data, that the methodology you choose for the research, influence what result you will get.

Investigate whether your local DPA or ethical committee has specific guidelines to ensure a sound research methodology.

4 Data Protection Rights & Challenges

A right to protection of an individual's private sphere against the intrusion of others, especially intrusion from the state, was first written down in an international legal instrument in Article 12 of the United Nations (UN) Universal Declaration of Human Rights (UDHR) of 1948 on respect for private and family life [21]. This action later influenced the development of other human rights instruments in Europe, and the right to data protection is now also to be found under Article 8 of the European Convention on Human Rights (ECHR) where it forms part of the right to respect for private and family like, home and correspondence [22]. The right to data protection is also regulated in Council of Europe (CoE) Convention 108, which is the first international legal binding instrument dealing with data protection explicitly [17:11]. EU law consists of treaties and secondary EU law. The treaties, such as the Treaty on the functioning of the European Union (TFEU), are referred to as "primary EU law". Under EU law, data protection was regulated for the first time by the Data Protection Directive, and it has now been acknowledged as a fundamental right [17:11]. The regulations, directives and decisions of the EU are referred to as "secondary EU law" [17:17]. The fundamental right to the protection of personal data under Article 8 of the Charter is not, however, an absolute right, but must be balanced against other rights in society[14], such as the freedom of expression[15], access to documents (access to documents is regulated in Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents [Access to Documents Regulation]) [23], and freedom of the arts and sciences[16].

Research ethics, and data protection is a lot about building trust. On the one side, trust is in fact a central component in the principle of fair data processing, and the main obligation is for the data controllers to demonstrate both vis-à-vis the data subject (the individual whose data is being collected/ processed) and the general public, that they will process the data in a lawful and transparent manner [17:77]. Furthermore, the processing should not happen in secret and should not have unforeseen negative consequences for the individual. In order to establish trust, the data controller should, as far as possible, comply with the wishes of the data subject. This is especially important if the data collection is happening on the legal basis of informed consent [17:77]. On the other side, it can be highlighted that although there are legal contractual responsibilities to research ethics and data protection, one aspect of this is also the fact that good research ethics can also be about building trust and best practise. This was mentioned by ESAB- member Petoussi after the second ESAB meeting. Research ethics can be seen (also as indicated by a contributor to the first Ethical Monitoring Report D95.31) as a formality that takes away effort and dedication to the "proper" work. Although there is no way to avoid this obligation, an alternative entryway to research

[14] See, for example, CJEU (2010), Joined cases C-92/09 and C-93/09, Volker and Markus Schecke GbR and Hartmut Eifert v. Land Hessen, 9 November 2010, para. 48. For more examples of relevant case law in this reagard, see pages 22-33 in European Union Agency for Fundamental Rights & Council of Europe (2013), Handbook on European data protection law. Publications Office of the European Union, Luxemburg.

[15] Freedom of expression is protected by Article 11 of the Charter ('Freedom of expression and information').

[16] Freedom of the arts is protected under Article 10 of the ECHR.

ethics is to consider it not only as “bureaucratic” requirements, forms and approvals, but rather as an opportunity to build trust. As contextualized by Kings College in London for example, the amount of small research studies and market ‘research’ recently has led to a reduction in the number of people agreeing to participate in such activities. However, by obtaining ethics approval you demonstrate that you have adhered to the accepted ethical standards for a genuine research study which could actually increase your recruitment potential [36], also in the long-run. Indirectly, this would contribute to pushing best- practise standards for research ethics.

Demonstrate both vis-à-vis the data subject (the individual whose data is being collected/ processed) and the general public, that you will process the data in a lawful and transparent manner.

4.1 Personal Data & Identification of “data subjects”

So what exactly can personal data mean? Under EU law (and CoE law), the definition of “personal data” is information relating to an identified or identifiable natural person [24], that is, information about a person whose identity is either manifestly clear or can at least be established by obtaining additional information. Both kinds of data are equally well protected in EU and CoE law. If data about such a person is processed in the course of the research activity, this person is usually referred to as the “data subject” [17:37].

Personal data can refer to practically all forms of information that a researcher might hold. Personal data is information which relates to a living individual who can be identified (a) from those data; or (b) from those data and any other information which is in the possession of, or likely to come into the possession of, anyone who may have access to it. Data protection principles are primarily concerned with information which is (a) held, or intended to be held, on a computer; or (b) held in manual records which are sufficiently structured so as to allow ready access to specific information about individuals. In other words, personal data refers to information that can lead to the identification of persons or opinions through material provided in interviews, workshops, questionnaires and that are written down and stored in handwritten notes or on computers.

Information does not have to be factually correct in order to be personal data. It is important to know that a person's identity can be obtained in different ways:

- **Directly** from identifiers such as names, addresses, postcode information, telephone numbers or pictures,

- **Indirectly** from identifiers which, when linked with other publicly available information sources, e.g. information about workplace, occupation or characteristics like salary or age.

It is not always given that the information that is being collected is collected indirectly or directly. For example if workshops are conducted, data recorded or a participants list is kept to reimburse participants afterwards, all of this is potentially data that may identify a person. Another example, of a source of data in DRIVER is the use of airborne sensors (UAV's) during experiments in SP4 or SP6. These may collect vast amounts of data that can potentially be used for identifying individuals directly- if the resolution of the camera is high enough. If the resolution is not so high that it can actually be used for direct identification of individuals (which is the case as foreseen in DRIVER at this point), identifying individuals indirectly through UAV's is still possible, because when linking together variables, such as movement pattern, with other public sources of information, such as workplace or residential address, can lead to the identification of an individual that fits those variables.

Be aware that personal data can be obtained directly, but also indirectly, and that both kinds are equally well protected in EU- and CoE law.

Example of an identifiability- challenge[17]:

Although not directly linked to research activities, the example below illustrates how an organization or agency (which could also very well be a research agency), need to pay close attention to whether the data collected is personal data, and how this data may be processed according to the relevant regulations and legislations.

A local authority decides to collect data via UAV's about cars speeding on local streets. It photographs the cars, automatically recording the time and location, in order to pass the data on to the competent authority so that it can fine those who violated the speed limits. A data subject (a person who owns a car that drives in those streets) files a complaint, claiming that the local authority has no legal basis under data protection law for such data collection. The local authority maintains that it does not collect personal data. Licence plates, it says, are data about anonymous persons. The local authority has no legal authority to access the general vehicle register to find out the identity of the car owner or driver. This reasoning does not accord with Recital 26 of the Data Protection Directive [24]. Given that the purpose of the data collection is clearly to identify and fine speeders, it is foreseeable that identification will be attempted. Although local authorities do not have a means of identification directly available to them, they will pass on the data to the competent authority, the

[17] This example is a slightly amended version of an example taken from the European Union Agency for Fundamental Rights & Council of Europe (2013:41), Handbook on European data protection law. Publications Office of the European Union, Luxemburg.

police, who do have such means. Recital 26 also explicitly includes a scenario where it is foreseeable that further data recipients, other than the immediate data user, may attempt to identify the individual. In light of Recital 26, the local authority's action equates to collecting data about identifiable persons and, therefore, requires a legal basis under data protection law.

However, if the data has been anonymised and does no longer contain any identifying factors that could lead to an individual being identified, then the data is no longer to be seen as personal data. There are different ways of anonymizing data. No use of high resolutions cameras that allow for the identification of individuals is foreseen in DRIVER at this point, and the need for potential anonymization relates mostly to personal data in a written format. In the example described above, it would not be useful to anonymize the data, since the purpose is for the authorities to identify traffic speeders and fine them, but in other cases, for example for the sake of protecting the anonymity of interview objects, one example of anonymization can be as follows.

Example of anonymization

Personal data: "Linda Frost is the mother of four children, two girls and two boys, and was born on November 12th 1979".

Anonymized data: "846, 1979, is the mother of four children".

If personal data is to be kept in its original form (e.g. for statistical purposes), then the Data Protection Directive (Art. 6 (1) (e)) and Convention 108 (Article 5 (e).) allow this possibility on condition that appropriate safeguards against misuse are applied [24] [25][18].

1.1.1 Sensitive personal data

Sensitive personal data is a kind of personal data that is especially regulated in both EU and CoE law. The concepts of sensitive data is defined in both Convention 108 (Article 6) and the Data Protection Directive 95/46 (Article 8) as being data that 1) reveal racial or ethnic origin, 2) reveal political opinions, religious or other beliefs or that 3) concern health or sexual life. For example, if an employer has a record that shows that an employee is 20% on a medical leave because of a broken arm; this is to be considered sensitive data because it says something about the health condition of an individual. In addition, the Data Protection Directive 95/46 lists "trade union membership" as sensitive data, since this can be an indication of political belief. Furthermore, Convention 108 lists personal data relating to criminal convictions, as sensitive data [17:44]. For the protection of sensitive data, the regular procedures for data protection, as described in Chapter 5, apply, but depending on national data protection guidelines, additional requirements may exist which can vary from country to country. In case sensitive personal data is being collected in DRIVER, the Data Protection Authorities in the country where the data collection takes place, needs to be consulted.

[18] See Chapter 8 of this deliverable.

Investigate what the local relevant procedures are for sensitive personal data in the country where the data collection takes place. Be aware that these procedures are stricter than those for non-sensitive personal data.

5 Data Protection Procedures

This chapter will clarify and give an overview of procedures that need to be followed in order to properly protect personal data (as defined in Chapter 4.1.1). The most common sources of data within DRIVER derive from reports and datasets, data gained from interviews, workshops and the testing of tools, and also data gained from larger experiments within DRIVER (the latter being explicitly addressed in Chapter 6). The rest of this chapter will focus on the two main procedural aspects that are important to keep in mind when conducting research ethically within DRIVER.

As described in detail in Chapter 4, compliance with data protection rules is an ethical as well as legal requirement for research in the EU. The partners in DRIVER have in many instances been given information about how to go about in order to ensure compliance with the relevant data protection rules. For example, in D95.21 (in M2 of the project), a questionnaire about data protection was provided to all DRIVER partners, which was intended to help the partners perform the first steps in assuring that the research is carried out in conformity with Special Clause 15 (see also Chapter 5.1) of the DRIVER Grant Agreement. Later, information about the relevant procedures was provided in the original version of this deliverable, D91.3 (in M6 of the project), as well as through comprehensive bilateral follow-up and guidance with individual partners in relation to the submission of the deliverables containing the ethical approvals (submitted in M6 and M18 of the project).

Before giving a detailed step-by-step example for how to obtain ethical/ data protection approval, the next chapter will explain what it is that the approval seeks to regulate, namely the safety and well-being of individuals partaking in the research activity, according to SC15.

5.1 Required approvals/notifications as set out by Special Clause 15

Although it is most likely (at this point in time- M20) that mostly approvals relating to data protection will apply to the experiments (in terms of *ethics* approvals that is- for flight permissions for UAV's, insurance, approvals from law enforcement etc., this is not the responsibility of PRIO), it is still possible that other kinds of ethics approvals might be needed. In the event that other kinds of ethics approvals should be needed, such as medical approvals, certain conditions need to be fulfilled. The ESAB highlighted that if medical- or health research is foreseen within DRIVER, that is the only likely context that would trigger other kinds of ethics approvals, which would require e.g. approaching an ethics board dealing with medical research[19] [7:8] [1:14].

[19] In Norway, for example, there are dedicated Regional Committees for Medical and Health Research Ethics (https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us=). These committees use additional ethical guidelines, see

Special Clause 15 (SC15, FP7 List of Special Clauses) states:

> *The beneficiary(ies) shall provide the REA with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out before beginning any REA approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the REA.*

In the following, some main practical implications of Special Clause 15, derived from D95.21 (New: D14.21) are explained. As Special Clause 15 applies to all forms of research, experimentation, testing and demonstration, this means that wherever human beings are involved in research activities, measures are to be taken to ensure their safety and wellbeing. Safety and wellbeing applies to those individuals who might be indirectly impacted by the research, and to those human beings that might be objects of the research through direct study, indirect observation, interviews, data collection or other means, but it also applies to the researchers carrying out the research. Measures to ensure the safety and well-being of individuals include the use of active, genuine and real informed consent and having the opportunity for follow-up talks and briefings after the activity has ended. Safety and well-being also refers to the secondary impacts of the research, experimentation, testing and demonstration upon uninvolved bystanders, the environment, economic conditions, and human development in general, etc. This means that any research needs to be reviewed with regards to their need for approvals. For that, D95.21 (New: D14.21) provides the first basic set of guidelines and serves as a supplement to this deliverable.

For the DRIVER project, Special Clause 15 refers to three different groups:

- The safety, well-being, and rights of *researchers*;
- The safety, well-being, and rights of *bystanders*;
- The safety, well-being, and rights of *research participants.*

All three of the ethical risk areas evoke the need for informed consent. Whether involved in the research as a researcher, a bystander or an active participant in the research, individuals have the right to be informed and fully understand the research in which they are involved. This right to be informed (which is seen as important for both the safety and the well-being of individuals) will be detailed in Chapter 7.2, but first we will give a practical step-by-step overview on what to do in order to 1) determine if your activity needs approval, and if needed, 2) how to get this approval.

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https://helseforskning.etikkom.no/ikbViewer/page/reglerogrutiner/loverogregler/annetgrunnlag?p_dim=34771&_ikbLanguageCode=us

The safety and wellbeing of an individual involved in the research, whether as a researcher, a bystander or an active participant in the research, begins with the individual having the right to be informed and fully understand the research in which they are involved.

5.2 Steps to take for obtaining ethics approvals

First and foremost, if needed, obtaining ethics approvals is the responsibility of the individual task leader, and should be sought at the most local level possible. This means that the Data Protection Authority/ Research Ethics Office/ Ethical Committee or similar in the country/ region where the activity is taking place or where the task leader resides should be consulted, given notification etc.

Any task leader conducting experiments or research activities that include the collection of personal data (see Chapter 4.1) or that otherwise require ethics approval thus has to conduct the following steps:

STEP 1: DECIDE IF YOU NEED APPROVAL

- By analysing the methodology of the task, the task leader will have to determine what kind of experiment or research activity that will be conducted.
    - The questions the task leader should ask are e.g. will personal data be collected? Will the general public be affected? Will the participants risk any harm?
    - Generally, if personal data is collected, data protection approval is needed (potentially only by notification).
    - For example, if the experiment is de facto a group interview, software testing or a table-top exercise (*in silico* experimentation), most likely only data protection approvals are needed, but potentially also approval to conduct research involving volunteers
    - Should the experiment involve the acting out of participants, a so-called "field experiment", PRIO should be consulted for potential additional follow-up.
    - Most experiments in need of ethical approval are also in need of data protection approval.
    - During the research activity, if individuals are at risk for harm (mental or physical), if personal data/ sensitive personal data is collected or if volunteers are involved in the activity, investigate whether approval is needed, and what kind of approval it requires.

STEP 2: IDENTIFY WHERE TO APPLY FOR APPROVAL

- The next step is to decide where to submit the application for approval/ notification.
    - In case the task is in need of approval (data protection or other), the task leader will have to identify the most local ethical authority that can issue data protection approvals and potentially other ethics approvals.
    - It is to be investigated whether ethical challenges other than data protection are regulated *via guidelines only* or *via approvals*.
    - If they are regulated via approvals the task leader will have to write an application that sets out the design of the experiment and reflects on how ethical guidelines are being taken care of methodologically.
    - Regarding seeking approval from Data Protection Authorities versus seeking approval from an ethical board or committee: unless the experimentation/ research activity involves participants acting out a scenario (what is also described as a field experiment) potentially taking place in the public, medical/ health data is collected, or the participant risk significant physical or mental harm by participating in the activity, it should be sufficient to get approval for the data collection [cf. 1: 14], but this must be decided in the individual cases.
    - If the activity does not collect or work on biological samples or medical/ health related issues, no ethics approval from *medical* committees is needed. However, in some cases medical committees, data protection authorities and other ethical committees are combined in one body that targets all kinds of research ethical questions.
    - Often, data protection authorities and other ethical committees are gathered in one authority and may issue both kinds of approvals, but this should be clarified in the different cases. National data protection commissioners are authorities with a specific focus on data protection issues, while e.g. university ethics authorities usually have a broader scope. In these cases, approach these bodies to learn about the responsibilities and rules for research ethics for experiments in your local context.
    - Some institutions have their own ethical advisory boards, such as large companies, universities, labs etc.[20].

[20] In Norway, for example, the Norwegian National Committees for Research Ethics (NESH) are independent agencies for questions regarding research ethics, and investigation of misconduct, within all subject areas. NESH mainly focusses on relevant ethical guidelines within different areas that should be followed to ensure good research ethics and "common decency".

STEP 3: SUBMIT THE APPLICATION/ NOTIFICATION

- The task leader will then have to issue the appropriate application, either for data protection approval- in case personal data may be collected, and potentially also for other ethics approvals.
    - In some cases these approvals may be combined[21].
    - In some cases, depending on the rules of the relevant DPA, it may be sufficient to submit only a notification to the authorities.
    - The approval has to be sent, or the notification submitted.
    - In some cases, it can be enough to be able to prove that you have submitted the application/ notification, before the start of the activity.
    - In other cases, the authorities foresee that the returned approval is at hand before the activity may start.
    - Generally, the application should be submitted as soon as possible, after you know what the research activity/ experiment will consist of. Remember what SC15 states: "The beneficiary(ies) shall provide the REA with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried *out before beginning any REA approved research requiring such opinions or approvals*[22]".

STEP 4: PARTICULAR TO DRIVER- UPDATE PRIO

- The final step is to notify PRIO about Steps 1-3, in order for PRIO to be able to carry out the continuous ethical monitoring of the project.
    - PRIO provides each year, all DRIVER partners with a calendar where the expected tasks that require approval are listed. This calendar is part of the annual deliverables in T95.2.
    - All partners are requested to update PRIO about whether the indicated tasks in the calendar are still valid, or if there are other tasks or activities that need approval and should be added.
    - The DPA or the relevant authorities should also be updated in case the research activity changes, for example if new kinds of focus groups are added or that the scope of the experiment changes significantly.
    - Each partner should send to PRIO the application submitted to the DPA/ ethical authorities, and the answer that you got to the application. PRIO will store all

[21] Note that also the DRIVER platform providers are Crisis Management professionals that are familiar with executing exercises as well as potential safety and ethics issues and will be able to provide advice as well.
[22] Author's *italics*.

these documents in a local folder, and these can be accessed by the ESAB, the PO/ the REA, or the Project Coordinator by request.

- If the answer back from the authorities is not received by the start of the activities, PRIO will store the application.

By following these four steps, the DRIVER partners pursue the recommended procedure to ensure that the research activity or experiment is conducted in an ethical manner. However, although these steps are necessary to uphold the ethical standards in DRIVER, following them is no guarantee that the research is ethically best-practise. This will always be reliant on the carrying-out of the activity, and is in particular the case when the DPA require only a notification about the activity, because this does not oblige the DPA to actively engage with the content of the activity.

The 3 (/4)- step procedure above is summarized in the table below:

Is personal data being collected?		
WHAT DO YOU DO?	**IF YES**	**IF NO**
Do you collect directly identifiable personal data[23]?	Data Protection Approval needed.	Data Protection Approval might be needed (see next question).
Do you collect indirectly identifying personal data (such as background material that might identify individuals)[24]?	Data Protection Approval needed.	Data Protection Approval not needed (if "no" on previous question as well).
Will personal data be collected via online forms (direct/ indirect/ via IP-address or email address)?	Data Protection Approval needed. Note that even if only the data processor has access to the identifiable information (such as an IP-log), approval is needed.	For the collection of data through online forms to be regarded as anonymous, neither IP-address, browser information, nor information capsules etc. can be used.
Will personal data be collected through digital images or video recordings (if faces are shown, it counts as personal data)?	Data Protection Approval needed.	Data Protection Approval not needed for this particular activity, but could be needed if linked with other directly or

[23] Such as name or national identity number. See Chapter 4.1 for definition of personal data. Note that even if the information is meant to be anonymized in the final report etc. the collection of personal data would still happen and thus the answer here should be "yes".

[24] A person will be indirectly identifiable if it is possible to recognize the person via a combination of background information (such as municipality or workplace / school, combined with data such as age, sex, occupation, etc.). For it to be counted as personal data, this must be recorded in combination with other information so that people can be recognized.

		indirectly identifying personal data.

Table 1: Is personal data collected?

Any DRIVER task leader conducting experiments or research activities that includes the collection of personal data has to conduct the following steps: 1) decide if you need approval, 2) identify where to apply for approval, 3) submit the application/ notification, and 4) update PRIO.

6 Information on sources of experimental data

The main procedure for testing and combining CM solutions in DRIVER is by the means of experimentation. Although "experimentation" can mean a number of things in different contexts, in DRIVER, an experiment is a scientific procedure undertaken to 1) make a discovery, 2) test a hypothesis, or 3) demonstrate a known fact [26]. In DRIVER, experimentation is done on man-made systems to test the hypothesis that a certain design works – and tries to discover problems and opportunities to inform the next system design phase[25]. Although the means of experimentation can be a source of data that might require additional ethics approvals beyond data protection[26], the most common kind of approval that the experiments will need, is basic data protection approvals. However, since it is likely that the crisis manager might not personally know the participants (such as volunteers) that take part in an experiment, and that their personal experiences and personalities are rarely known beforehand, there is also potential risks that goes beyond the data protection issue, and that could affect individuals in a different way.

For example, the scenarios that make up the experiment design could be implemented in a way that could make the participants disproportionally surprised or distressed, e.g. due to the brutality of them. Obviously, a certain "surprise- element" is necessary to conduct realistic trainings, but the key word here is "proportionality" and the potential severity of negative impact it can contain. Furthermore, the basic psychology of crisis exercises is briefly described in Chapter 3.1.1 of the first Ethical Monitoring Report (D95.31), and mentions one example of unintended effects of a crisis exercise. This was a situation where a hostage situation was being played out in a high school. The older students had been allowed to watch as the exercise took place, and while it was not particularly violent, shouting and threatening behaviour took place during which one girl in the crowd started crying and became very upset. It turned out that she was deaf, and none of the crisis managers in the exercise had explained to her what was happening [27] [35].

In the following, we will detail a bit more on what the DRIVER experiments will imply for the concept of research ethics in the project. Note that the following is not aiming to be a full typology of the experiments, taking into account the technical or practical traits of the different categories of experiments, but it is merely a set-up to help PRIO in expecting whether or not some experiments in DRIVER may require additional approvals beyond data protection as mentioned above. Regardless of the accuracy of the typology, it is nonetheless still the task leader/ experiment leaders responsibility to investigate whether approval is needed, and to eventually apply for it.

[25] Draft DRIVER terminology (under drafting per December 2015- not to be circulated).
[26] It may be the case that some type of additional ethics approvals may relate to the participation of members of various agencies (police, fire fighters etc) who may need approval/permission to participate. This may probably need to be kept under consideration for future research activities.
[27] This example is taken directly from Chapter 3.1.1 of D95.31, and derives from a real- life example described by Løvik, K. (2010:60), *Øvelse gjør mester.* Kristiansand. Høyskoleforlaget.

6.1 The DRIVER Experiments

The DRIVER experiments can include a range of activities, meaning anything from interview and workshop sessions to acting out a scenario, all of which is covered in this deliverable. Because the term "experiment" is rather common, also in everyday language, and relates to a number of things in the DoW, it is important to use this term with care. In the original DRIVER DoW, experiments are mentioned as involving methodologies (in WP22) and states that an experiment can also include "just interviews" or "data collection", which will be the main research activities in SPs 3, 4, and 5. To shortly describe the nature of the DRIVER experiments: the CM-solutions developed in SPs 3-5 will be tested in smaller experiments during the first phase of DRIVER (SE1 and SE2). The solutions will then feed into more complex joint experiments (JE1 and JE2) that will run in parallel in SP6, using a test bed provided by SP2. These experiments will be more advanced in terms of complexity and operational realism. The campaign of experiments in JE1 and JE2 consists of a series of experiments in which typically a cluster of promising ideas are tested, assessed and benchmarked in realistic conditions with real users, sequenced so that each experiment provides an additional step towards a refined operational solution. A final demo (FD) will demonstrate the improvements that the experimentation with the DRIVER solutions has had on crisis management practices.

The implementation and testing of the DRIVER crisis management solutions happens in three fictitious contexts, where additional levels of complexity are added by combining different solutions in more demanding CM scenarios in two so-called Joint Experiments and a Final Demo:

- Joint Experiment 1 (JE1): Flooding with cascading effects
- Joint Experiment 2 (JE2): Heat Wave with cascading effects
- Final Demo (FD): Mediterranean tsunami

Both the joint experiments and the demo will cover all levels: local, regional, national and pan-European level and (in parts) UN-level, and also all levels of decision-making from operational to strategic. They will involve solution providers and operators with their legacy systems, citizens and volunteers, the DRIVER test-bed from SP2 (platforms, test-bed solutions, methods, people and ideas[28]) and solutions based on the research and experiments in SP3-5. It is yet to be decided if the Joint Experiments and the Final Demo may require approval beyond data protection, as the design of the scenarios are still being planned, but PRIO is following this process. We have no indication that additional ethics approval will be necessary at this point. In general, the experiments within DRIVER mainly happen on the basis of *tactical command & control coordination*. The focus is essentially on the tactical level, and is aimed at testing out the CM solutions that are being developed and deployed throughout the project with regard to different needs and questions. This happens in various ways,

[28] Cf. WP21- Coordination and Objectives of Test beds.

e.g. through solution-testing followed by an interview with the operator, and other training activities, e.g. for testing a decision-making process tool. Such tactical coordination experiments are to a large extent mainly required to adhere to data protection legislation and the general research ethics principles.

A checklist/ list of general recommendations for the DRIVER experiments is provided in annex to this deliverable. In addition, D23.11, the DRIVER Experiment Design Manual is a manual to be used (and developed) by all partners in DRIVER to ensure that experiments are systematically designed, are cost effective and conducted in an ethical manner and that they produce the evidence needed. In Chapter 11 of this deliverable is a list of ethical recommendations for research in experiments. This serves as an input to the Experiment Design Manual (in annex to D23.11). In this way, ethical considerations are implemented directly into the design and carry-out of the experiments.

1.1.2 Typology of experiments

There are many ways to differentiate between different experiments, and the reason for doing so here is to make it easier for PRIO and the partners to decide what kind of ethics approvals an experiment might need. As mentioned above, the typology below would most likely look different for someone doing the exercise for the purpose of assessing technical functionalities or for someone assessing the cost-effectiveness of the experiment set-up. Consequently, the typology of the DRIVER experiments in this deliverable is chosen to allow for the most relevant analysis in terms of research ethics. Concretely, the typology must result in an indication of which kinds of approvals it might trigger and what potential other ethical considerations might be relevant.

In our everyday understanding of "experiments", they often refer to scientific method, commonly used within disciplines such as psychology, chemistry, medicine and sociology. It is a systematic and scientific approach to research in which the researcher manipulates one or more variables, and controls and measures any change in other variables. Within the DRIVER project, experiments mainly relate to the collection of data that feeds into the development of a measure or solution, or any research method that involves the testing of a developed measure or solution. As the term "experiment" is used broadly within DRIVER and may include a variety of research activities, giving specific recommendations for a general term is difficult. However, based on current understandings of anticipated activities, some advice can be given. Occasionally the DoW mentions *experimenting through the conduction of workshops and interviews* as a form of experimentation. Such workshops will mainly require adherence to the relevant data protection legislation, regarding the collection, storage and processing of (personal) data derived from the workshops (e.g. participation lists or recorded information, cf. Chapter 4.1). Other than that, there are three kinds of experiments foreseen within DRIVER:

1) Experimenting through **table-top** experiments (e.g. in T52.3). This can be simple paper-based exercises aimed at particular groups within an organisation. These experiments do also primarily require attention to principles of data protection, although they might differ from

workshops as they might request participants to engage in, scenarios and simulated situations- *in silico*. This could mean that participants don't act out a crisis situation, but enter their (expected) movements into a computer system. Instead of a real life crisis, the situation is steered by a computer system and any movement is registered here and not play-acted. These experiments furthermore require adherence to the general principles for ethical research set out in Chapter 4 and 5.

2) Experimenting through the **testing** of CM solutions (e.g. in T32.4). This is a more hands-on approach to experimenting, as the solutions that are being developed will be tested in actual and relevant environments. This will mainly happen within a closed and controlled professional environment. This can for example be in the shape of simulation exercises where a scenario has been prepared in advance, and the team is responding to it. This would be more realistic and operational than a table-top experiment, but usually does not require any additional ethics approvals other than data protection and the adherence to the general principles for ethical research set out in Chapter 4 and 5. This kind of experiment can also be referred to as "input-response simulation" [27].

3) Experimenting through playing out a situation in a **field- experiment** (can be referred to as a "full-scale exercise" [27], meaning engaging individuals in acting out a real- life scenario according to a number of variables with an unpredictable outcome. The participants in this kind of experiment can be both internal and external. It is unsure at this point as to which degree this will happen within the scope of DRIVER, and what the likely nature of such experiments would be. This genre of experiments or exercises are regularly conducted by emergency services, and can include e.g. visual effects (such as smoke or fake blood etc.), fully equipped emergency personnel (such as vehicles or weapons) and volunteers acting out distress or injuries (often with fake injuries or wounds to increase the level of realism). In general, particularly if they are conducted publicly, and could implicate potential physical or mental harms to the individuals involved, this kind of experiments could require ethical follow- up besides the standard data protection and informed consent- routine that implies for the other kinds of experiments. Although unsure at this point, this is foreseen to be mainly potentially relevant for SP6[29]. The planning of the activities that will be part of the Joint Experiments and the Final Demo will be analysed accordingly.

In case participants risk harm or the public is affected by the experiments, it is likely that ethics approvals beyond data protection are needed. Consult PRIO or the relevant authorities for guidance.

[29] Currently it is not foreseen that there will any potential dangerous activities carried out within DRIVER. In case the further planning of the experimentation in SP6 reveals any upcoming ethical problem related to a planned activity, the activity will most likely be skipped.

In sum, for all three kinds of experiments described above, attention regarding ethics should be given to the following:

- ✓ Informed consent (see Chapter 7.2 for details) needs to be collected from all participants.
- ✓ In addition to the normal data protection approvals that are most likely needed for collecting data (including experiments), there might be a possibility that other ethics approvals are needed and that particular guidelines need to be followed, which are set out by national ethics bodies, *if the experiment has traits of the third kind of experiment described above*.
- ✓ Other ethics approval might be needed if additional measures are necessary to protect the health, well-being and security of researchers and bystanders subject.
- ✓ In some countries, regulations concerning the health, well-being and security of participants and bystanders are only handled on the level of guidelines; in others the conduction of an experiment requires an actual approval.
- ✓ In most cases, the question of approval is dependent on the danger that the experiment participants are exposed to, and the proportionality of the risk it includes, for example when they act out specific situations that can put them in danger, psychologically or physically.
- ✓ If an experiment is planned for a semi-public space, potential distress of bystanders should be minimized by putting up informative posters or by otherwise seeking to inform the public[30].

[30] Highlighted by the ESAB. See D95.12 (New: D14.12).

7 Recruitment of participants in research

The main rule for the recruitment of participants for research activities and experiments is to always ensure that you have obtained full, genuine and active informed consent from the participants. This means for example that there should be no undue pressure to participate by the agencies to their members, either to participate or not to participate. In the following chapter, we will describe a bit closer how participants are taking part in the DRIVER research activities, and what considerations need to be made in this regard. After each relevant paragraph, a list of recommendations and considerations is presented.

7.1 Participants

As a very general rule, when conducting research on or with human participants, it is important to minimize harms and risks and maximize benefits. For example, human dignity, privacy, and autonomy[31] needs to be respected, and the research should take special precautions when it e.g. deals with vulnerable populations. In the guidelines for how to complete the ethics self-assessment in the context of H2020, it is stated that if the research activity includes several ethical concerns or involves several significant or complex ethical issues (such as participation of children from developing countries, NHPs, potential malevolent use or vulnerable populations) it is suggested to appoint an ethics advisor or ethics advisory board with several experts with varied expertise[32]. In DRIVER, such a board exists, and the ESAB will be consulted in difficult cases, for example concerning vulnerable populations or individuals. Although the inclusion of vulnerable individuals must be investigated in the respective relevant cases (guidelines may vary across countries), as a general rule, the researcher needs to demonstrate appropriate efforts to make sure that the participants fully understand the implications of their potential participation in the activity. With regards to harm, there are two important questions that the researcher could ask to assess the risk of harm. First, the researcher could ask what the probability of the harm is. The lower the risk, the better, but this can be very difficult to estimate. Secondly, the researcher could ask what the worst case scenario would be. How serious might the harm be if it occurs? The researcher should also be aware of the fact that "harm" could mean different things to different individuals, and some examples are distress, embarrassment, humiliation, and anxiety. [30]

As we have already described, when participants are part of the research, it is possible that additional approvals, relating to additional ethics issues are needed. This is only the case when the participants face the chance of being harmed or hurt, either physically or psychologically, or if

[31] For a more detailed discussion about these terms (and several other criteria used to describe the societal impact of the DRIVER activities) see D84.21- A guide to unintended societal impacts of different CM functions- Version 1.

[32] This information can be found on page 1 of "How to complete your ethics Self-assessments" in the context of Horizon 2020, provided by the European Commission (2014).

medical/ health data (such as blood samples or information about medical history) is being collected. For example, it may be necessary to obtain medical approvals to ensure that the involved participants are mentally and physically prepared for the unpredictable nature of the research. However, as far as the planning of the experiments are at this point of the project (M20), no "research on humans" is foreseen within DRIVER, meaning no experiments on human tissues, cells or the human psyche will be conducted.

However, should the experimental research *have* the potential to induce psychosocial effects of some kinds, this should be included in the application to the DPA or ethics committee. These committees also set the conditions for the use of the consent, and may require the project to obtain new or additional consent if the committee deems it necessary. As previously mentioned, the testing of solutions and table-top research are the main experimental research taking place. Although these kinds of experiments do not generally require ethics approvals besides protecting the privacy of the participants, some precautions should be taken when including participants in the research (valid for *all* kinds of experiments).

When including participants in the research:

- ✓ Identify as exactly as possible, what is being done in the experiments, and inform the participants as well as possible (without undermining the nature of the research activity or experiment). Judge whether certain parts of scenarios should be shared with participants in advance to avoid potential negative impacts on the participants.
- ✓ Obtain active full and real informed consent (more details in Chapter 7.2)
- ✓ If you need participants to play-act, aim at using professional volunteers, meaning pre-organized volunteers from e.g. the Red Cross or THW that have been properly educated and where insurance questions are clarified. Volunteers from these organizations would in addition have the added benefit or value of being aware of some procedures when it comes to handling a crisis during the experimentation, such as first aid.
- ✓ Proper insurance also needs to be in place, to safeguard against potential loss or injury. Should you not be able to use professional volunteers, but civilians, aim to invite civilians organized in a sports club or similar, as these are likely to already have the necessary insurance in place through their organization[33].
- ✓ Ensure diversity among the participants in the sample. Practically, this means that extra attention needs to be given to creating a balance among the participants regarding gender, age and other demographic variables. This is important to ensure that the outputs of the research (the results) are generalizable and transferrable, and that they reflect a picture of reality that is as accurate as possible[34].

[33] However, these kinds of precautions do not formally fall under the scope of PRIO, but are the legal responsibility of the experiment- or task leader.

[34] Research show that Latinos are under-represented in biomedical research conducted in the United States. See for example Ceballos, R.M, Knerr, S., Scott, M.A., Hohl, S.D., Malen, H., Thompson, B. (2014), Latino Beliefs about Biomedical

7.2 Informed Consent

When it comes to the recruitment of participants for the different research activities within DRIVER, it is important to pay attention to a couple issues to ensure that the collaboration happens lawfully, and ethically. The most important consideration when including individuals in research is the concept of informed consent. Research shows that participants are more willing to participate in research if they have been fully informed [cf. 31]. This chapter will detail what we mean by informed consent, how it can be obtained, and why it is important.

The large majority of the partners that have given input to D95.31 reported that they had used or are planning to use the informed consent template provided by PRIO in the original submission of D91.3, indicating that most partners have encountered or reflected upon the issue of informed consent already in M6 of the project. Informed consent means "any freely given specific and informed indication of the data subject's wishes" [27: Article 2 (h).]. In many cases, it is the legal basis for the legitimate processing of data [17:56]. Concretely, all individuals participating in the research activity or experiment have the right to be informed, and to fully understand the content and extent of the research which they are involved in. This responsibility by the researcher is expressed in the following way:

> *Not obtaining the appropriate informed consent, is not only exercising poor research ethics, but it is also a breach of the contractual agreement through the Special Clause 15. Failure to properly and fully address issues of informed consent may unnecessarily restrict the usage of data, publishing results and sharing data [29], or may even result in a disapproval of the task by the European commission/project officer (see also D95.21).*

In order to safeguard the abovementioned right [cf. 17:56], there are some key points that the researcher should pay attention to. The most important principles when it comes to informed consent are:

- ✓ Never expose people to a potentially alarming situation without getting at least a general consent[35].
- ✓ Consent, as a legal basis, must be free, informed, and as specific as possible.
- ✓ The consent must be given unambiguously, without hesitation or doubt.
- ✓ For the collection and processing of sensitive data (cf. Chapter 4.1.1), explicit consent should be obtained, detailing exactly which data will be collected, how it will be stored, processed and deleted.

Research Participation: A Qualitative Study on the US-Mexico Border. *Journal of Empirical Research on Human Research Ethics* 9:4.

[35] Highlighted also by the ESAB. See D95.12.

- ✓ The individual must be informed that the consent can be withdrawn at any time of the research (also after the informed consent form has been signed).
- ✓ There must be active communication between the parties. This means that consent must never be inferred from a non-response to a communication, such as a letter [29].
- ✓ To ensure that consent is informed, consent must be given freely with sufficient information provided on all aspects of participation and data use.
- ✓ You should also give participants the possibility for "whistle blowing". For example, should a participant develop serious doubts regarding the research ethics of the project/ activity, the responsible researcher must ensure that he or she is allowed to present his or her worries to an independent consultative body, such as the DRIVER Ethical and Societal Advisory Board. This can happen through the Ethical Monitoring Report or by contacting task leader PRIO. It is furthermore important to make this option known in advance.
- ✓ It is very important that the researcher takes the time to listen to the participants concerns about what worries them in the activity/ experiment [30], but it is obviously difficult to pinpoint every potential harm, as participant could e.g. be upset by a certain question without the researcher having any chance to discover that in advance[36]. Nevertheless, a researcher should attempt to predict and safeguard against all reasonably predictable harm, risk or burden to participants. A best-practised research ethics is meant to avoid such incidents [30].
- ✓ Tailor the informed consent forms to the specific research context, stating the methods and sample, the nature of the data (personal, sensitive, level of detail), the format of the data (surveys, written, recordings) and the planned data processing. This will influence the type of consent and consent process used [30].
- ✓ Ask yourself whether informed consent is obtained from the participants in a reasonable manner and whether it is evident that no dependency relations influence the participant's consent.

The description of valid consent in EU law includes three elements that must be present for the consent to be satisfactory. All of these need to be fulfilled in order for the consent to be valid according to data protection law [17:57]. These may serve as sort of a summary of the list above:

- ✓ The data subject must have been under no pressure when signing the consent form.
- ✓ The data subject must have been well- informed about the purpose and consequences of consenting to the activity.
- ✓ The scope of consent must be reasonably concrete, in order for the data subject to form a good picture of what the situation is.

[36] Although harm and the risk of inflicting harm is almost impossible to estimate or predict, harm could mean a number of things. In either case, it is subjective, for example it could mean that the participants are being embarrassed, distressed or anxious. This can for example happen if the participants feel that their values have not been respected.

Furthermore, the question is what exactly the informed consent form should include. Principle rules include that the participants, before taking part in the research, have the right to be informed[37] at the minimum about the following:

- ✓ That participation is voluntary.
- ✓ That they may ask questions and receive understandable answers before making a decision about participation.
- ✓ The degree of risk and burden involved in participation.
- ✓ Who will benefit from participation?
- ✓ That they may withdraw themselves and their data from the project at any time.
- ✓ That they are given a channel or a person to contact in case they have doubts about their role or the project.
- ✓ How their data will be collected, protected during the project and destroyed at the end.

Concretely, the quality of the consent is an important issue. This has to do with the fact that the consent needs to be given actively by an individual that has had the opportunity to make a real choice, and give real consent. Deducing consent from mere inactivity is not sufficient [17:56]. The limits of active consent are when a participant can give consent 'too easily': consent forms on mobile phones are a classic example of forms in which information is either not properly given or not read actively before consent is given. The quality of the consent can pose a problem if the individual participating in the research activity (e.g. the workshop or experiment), is instructed to do so by his or her employer. In this case it is particularly important to make sure that the individual's right to withdraw herself and/or her data is clarified. The data can be withdrawn up to a certain stage of the research process, usually until the data had been anonymized or encrypted. If you gather video, audio or other visual data (e.g. airborne sensors), the anonymization of data is often impossible. Getting informed consent from the participants in such instances is even more important. Should the individual choose not to participate, it is important to point out that there will be no consequences for the individual. The following paragraph illustrates some of the nuances in the ethics of an organization in terms of consent:

> *Research with people within an organization or workplace will need additional consent if work is to be discussed. Information given by an employee in an interview which takes place during the course of employment (typically on the work premises) should not be used unless the employer has given consent. This is because employees may be seen to owe a duty of confidentiality to their employer. Indeed employment contracts may contain confidentiality clauses. It is always advisable when carrying out research with someone in the workplace, in*

[37] See Annex 1 for the « Informed Consent Form template » produced in D95.21 (New: D14.21).

working hours, to discuss whether consent from employers is necessary. It is the responsibility of the researcher to be aware of the policy of each organization [29].

Get *active* and *real* informed consent, inform about the right to withdraw, and facilitate "whistleblowing".

Disclose as much information as possible in advance to the participants in order to minimize the risk of harm through unforeseen uncomfortable questions.

8 Security Measures

While the ethical obligations toward good research conduct in DRIVER may not differ from those encountered in other research projects, the size of DRIVER, i.e. the number of participating organisations of several countries as well as the size of the two joint experiments, may give rise to specific ethical problems that are generally less prominent. This chapter will discuss how to safeguard against the misuse of acquired data, how to limit intrusion into the public and mitigate risks to privacy.

8.1 Misappropriation of Data

A lot of the data collected in DRIVER will be of great interest to those working in the large field of crisis management, e.g. as technology providers, researchers or governmental agencies. While it is thus tempting to use this material for additional projects and further analysis, this practice violates good ethical research conduct. This section will address how to mitigate the risk that data is used improperly.

One of the central elements in good research conduct is the adherence to strict rules regarding the protection of privacy of participants. This includes the obligation to process data in accordance with individuals' rights. Individuals have (a) a right of access to personal data held about him/ her; (b) a right to prevent the processing of personal data which is likely to cause damage or distress to the individual; (c) a right to prevent the processing of personal data for the purposes of direct marketing; and (d) a right to require that no decision that significantly affects the individual is based solely on automatic processing of personal data [34:9].

In terms of handling data, it is crucial to ensure confidentiality towards both informants and participants. Further, the data needs to be stored in a correct manner. For some projects it is a requirement that data is stored for a long time. Make sure that the data is stored securely and proportionally to the purpose, meaning: don't collect too much or insufficient data, or data that does not answer the purpose of your research [34:9]

As mentioned before, participants' informed consent is a general and very important rule for all research activities being carried out (cf. Chapter 7.2). It is also important to ask for explicit consent when gathering sensitive data. Explicit consent involves obtaining a signature for an interview or a statement when recording an interview. Personal data gathered during interviews or other research and demonstration activities should always be treated confidentially and stored only as long as necessary. In some cases, it might be necessary to directly provide anonymity of information or to

anonymize data after collection[38]. In case personal data is stored after the task for which it has been collected has ended (e.g. for the DRIVER community data base) it should be carefully taken care that it is not being used for any purpose other than the one agreed to by the individual owning the data (the reverse could be called "mission creep"). Data has to be destroyed as soon as the individual owning the data wants it to be deleted. Task leaders are generally responsible to verify the use of the data and the destruction of it after the project has ended or when the individual participants ask for it.

Personal data gathered for research purposes within the DRIVER project should only be re-used if the individual owning the data agree to it. In other words, should personal data be re-used for other purposes that originally intended, explicit consent needs to be sought from the individual that owns the data. Further, it should be thought of any potential mission creep involving the data gathered during the project, i.e. of any potential of using the data beyond the project's benevolent intentions that could violate the privacy of participants (and researchers). After a research activity that involved participants has ended, it is important to facilitate de-briefing (cf. also WP23). This is not only to gather additional data and research results, but to enable a full understanding of the situation for all participants and potential expression of disagreement and withdrawal from the project (or informed continuous participation).

Beyond the data handling and use in research, good research ethics also extends to the physical security of personal data. Data needs to be securely stored. Are physical data kept in a secure and locked room? Who has access to them? Is access monitored via CCTV or other recording equipment? Can they be removed from the room? But also: how to dispose of paper with data? How secure is portable equipment (e.g. laptops and any storage media or devices)? Computer security is constantly evolving and may require advice from a specialist, depending on the complexity of the particular case. Make sure to use encryption and password protection where necessary and keep virus protection software up dated. Data should not be stored for a longer time than what is necessary, and it should eventually be deleted or destroyed**.** Annex 2 contains a template for Research Ethics Approval Applications.

[38] 'Confidentiality' and 'Anonymity' are not synonymous:

"Confidentiality"
Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

"Anonymity"
Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants' identities. A study should not collect identifying information of research participants unless it is essential to the study protocol." Virginia Tech. Institutional Review Board. http://www.irb.vt.edu/pages/confidentiality.htm, retrieved December 08, 2015.

Given the diverse range of national data protection and ethical guidelines of countries associated with DRIVER, it is important to adhere to the strictest, not the most lenient, rules and take those as the standard for all activities. The main guidelines and procedures for data protection can be found in Chapters 4 and 5 of this deliverable.

8.2 Protecting Privacy by Limiting Intrusion

The joint experiments in DRIVER pose additional challenges to good ethical conduct as they might gather information from people who are not part of the experiment and thus have not been briefed and whose consent has not been received. Precautions need to be taken to limit both the exposure of bystanders to the experiments as well as limit the data taken from them.

As a general rule, technology for data (or picture) recording, including tracking of location or observation of people should only be used if strictly necessary for the success of the research activity. If not avoidable, measures for minimising intrusion of researchers, participants and bystanders should be installed. In any case, the usage of such technology must be justified. Within the context of DRIVER, it is most likely that tracking of location will be relevant in connection to the use of mobile applications (e.g. to monitor traffic to discover bottlenecks). The tracking of location is not initially a problem, but the main consideration it to make sure that everything happens according to active and real informed consent. For example, it should not be made as a default function in the application.

The DRIVER experimentation and the final demo may for example include (picture) recording of people that are taking part in the activity or of bystanders. In this case it is important that everyone being recorded is being informed about the recording and has the opportunity to refuse being recorded. Experimentation and demonstration activities should be limited to a clearly defined terrain and information about the conduct of recordings has to be clearly displayed so that people who do not wish to be recorded can refuse to be part of the activity.

Only use technology for data recording, if absolutely necessary. Provide justification, and make the conduct of observation or recording of people very clear.

Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research.

Give anyone potentially affected by it the possibility to refuse from being observed or recorded.

9 Potential Risks and Challenges for ethical research

In this chapter we will present a few examples of potential scenarios where the subtle difficulties of research ethics are visible. These will also illustrate that it is difficult to give one-size-fits-all recommendations for all research activities and experiments within DRIVER, since the situations and contexts will indeed vary across sectors, countries and organizations.

The examples are not drawn directly from the DRIVER experiments, but are meant to illustrate the complexity of research ethics[39].

Scenario # 1

An unaffiliated volunteer in an experiment receives an informed consent form, and is asked to read and potentially sign it. However, the volunteer doesn't understand the content of the form (for example because he cannot read) and is too embarrassed to let the organizers know in front of everyone.

- Recommendation: Make sure that all participants are given the chance to let the researchers know about potential questions and constraints in advance of the research activity, for example by providing for a phone number that potential participants can call in case they have any questions. Offer to go through the informed consent forms together with the participants.

Scenario # 2

A volunteer in an experiment who is not fluent in English is given an informed consent form prior to the start of the experimentation activity. However, because of the complexity in language, the volunteer doesn't understand the content of the form, but he signs the form anyways. After the start of the activity it is revealed that the volunteer is feeling uneasy about the experiment he is taking part of.

- Recommendation: If there is any doubt about whether or not a participant in an experiment fully understands the content and procedure of it, use an interpreter to ensure full understanding. If this cannot be guaranteed, consider stopping the cooperation with the participant in question. It is not worth to gamble with the obligation of informed consent.

[39] Some of the scenarios are inspired by examples found in [33] "Examples of ethics dilemmas".

Scenario # 3

As part of an experiment, a group of volunteers are being recorded on video while working together to solve some challenges. After the study has ended, one of the participants in the group decides that she wants to withdraw from the study, and withdraw her data as well. For the researcher, this is unfortunate, because if he is to withdraw the data from the relevant participant, he would lose also the footage of the rest of the group since all the footage shows the interaction of the whole group.

- Recommendation: The researcher could offer to the participant to, instead of deleting the full footage, to only analyses/ use the interactions in the footage that does not include the participant that has withdrawn. If the participant does not agree to this solution, it is the right of the participant to request that the full footage is being deleted [32].

Scenario # 4

An affiliated volunteer (who is a member of a volunteer organization) is participating in a crisis management experiment divided into five separate sessions. After the fourth session, the researcher learns that the volunteer has withdrawn from the organization and does no longer wish to be a volunteer. Although we cannot know if the experiment activity influenced (directly or indirectly) the volunteer's decision to exit the organization, there is a chance that this is the case. This could happen e.g. if the experiment has demonstrated the harsh reality of a (potential) crisis situation in a way that the volunteer maybe didn't foresee for himself/ herself, thus startling him/ her from continuing her participation.

- Participating in an experiment can have unintended consequences beyond the end of the immediate activity. If the researcher suspects that a participant in an experiment has withdrawn her affiliation to the crisis management organization as a reaction to the experiment, make an effort to get in touch with the participant, e.g. to explain that her information is being treated confidentially. However, be careful not to inflict pressure on her, and be aware that it is the right of the participant to withdraw from the study without giving any reason. This example also demonstrates the importance of giving as much information about the experiment to the participant in advance, and to clearly explain their rights.

Scenario # 5

When compiling a deliverable, a researcher wants to use sections from academic literature to illustrate a point. However, the sections the researcher use are more or less a copy and paste exercise, and is not properly referenced. Another researcher (or a reviewer) in the project reads this deliverable, and accuses the researcher for plagiarism.

- Plagiarism is a serious issue, and the most common ethics issues also includes the "avoidance of any breach of research integrity, which means, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct" [34]. In order to avoid plagiarism, make sure to always quote in a proper manner all sources and

literature in a written text (such as a deliverable). Be aware that reviewers use or are likely to use, plagiarism solutions or plagiarism checkers. In general, erring on the side of safety is recommended.

Scenario # 6

A volunteer has decided to take part in an experiment. He is not told exactly what the experiment will consist of, only where and when it will take place. He then learns that to partake in the experiment, he has to download an application to his mobile phone, from which he will receive instructions during the experiment. In order to download the application, he has to sign an informed consent form within the application that consists of a very dense text in small letters. The information is so complicated and dense that he has problems reading it, and in order to take part in the experiment, he ticks the box indicating that he has read and agreed to the terms and conditions, even though he has not properly read them. Later, during the experiments, he discovers that the experiment turned out to be something that he is not really comfortable with partaking in, something he could have discovered from reading the full informed consent form.

- This scenario highlights the importance of getting *active* informed consent, and that it is not to be considered real and active consent if a participant can give consent "too easily". One solution, while of course keeping the full text with all the full-length terms and conditions, could be to break down the information into sub-chapters, and make the participant rather "tick off" boxes with the most important (i.e. most intrusive or invasive to the person) after each chapter or topic is covered. This will take more time for the participant, as it obliges him/ her to engage actively with the text (or at least he is more likely to), but will also be more likely to result in *active* and *real* consent.

Scenario #7[40]

In an experiment, a drone (UAV) is used to collect data in the border area of two neighbouring countries. The drone collects video images, and transfers them back to a central in one of the countries. After the experiment is finishes, the data is stored in a third country, because an organization residing in this third country owns the exercise. Who should then apply for data protection approval?

- First, it is important to determine whether the drone collects data that allows for the identification of individuals, either because of high resolution or because the stored information allows for a deduction (e.g. by seeing someone in a specific environment or a specific group of people). If it can be confirmed that this is not the case, approval may not be necessary. Should it be unclear who should be applying for approval in such a case, the Ethical and Societal Advisory Board's advice is to encourage those partners with expectably the highest national standards to apply in their country [7:16]. Through that, a best practice in research ethics can be guaranteed.

[40] This scenario was discussed in the second ESAB meeting, and is referred to on page 16 of D95.12.

10 General Recommendations for Ethical Research[41]

Below, lists summarizing all the DRIVER Recommendations for Ethical Research in different areas and with different focuses made throughout this document can be found[42]. It serves as a summary and overview for DRIVER partners to ensure that following research ethics, which in itself a complex matter, can be done by following concrete recommendations.

GENERAL RECOMMENDATIONS FOR ALL RESEARCH IN DRIVER:

- ✓ Aim for high ethical standards. This is important because the rationale behind such standards includes principles and safeguards that, if not upheld, would put the very foundation of research at risk. Safe and sound research activities contribute to accountable and legitimate research outputs.
- ✓ Reflecting upon terms such as *transparency*, and *accountability,* which govern the relationship between the researcher and the individual whose data is being collected, can create a better understanding of the concept of research ethics.
- ✓ Take into account in the analysis of your data, that the methodology you choose for the research, influence what result you obtain.
- ✓ Investigate whether your local DPA or ethics committee has specific guidelines to ensure a sound research methodology.
- ✓ Demonstrate both vis-à-vis the data subject (the individual whose data is being collected/ processed) and the general public, that you will process the data in a lawful and transparent manner.
- ✓ Be aware that personal data can be obtained directly, but also indirectly, and that both kinds are equally well protected in EU- and CoE law.
- ✓ Investigate what the local relevant procedures are for sensitive data in the country where the data collection takes place. Be aware that these procedures are stricter than for normal data.
- ✓ The safety and wellbeing of an individual involved in the research, whether as a researcher, a bystander or an active participant in the research, begins with the individual having the right to be informed and fully understand the research in which they are involved.

[41] Although these lists aim at being a through guide on how to conduct research in an ethically sensible and good manner, PRIO does not claim that they are complete in all cases, or that there are not potential aspects missing that could be relevant in certain cases. However, the lists (also in Chapter 11) provide a general guide, and a starting point, both for adhering to central rules and regulations, as well as working as an awareness- raising exercise that could result in a partner realizing ethics issues where none were seen before.

[42] These recommendations are not only from the text boxes, but also from the smaller lists of recommendations throughout the document.

- ✓ Any DRIVER task leader conducting experiments or research activities that includes the collection of personal data has to conduct the following steps: 1) decide if you need approval, 2) identify where to apply for approval, 3) submit the application/ notification, and 4) update PRIO.
- ✓ In case participants risk harm or the public is affected by the experiments, it is likely that ethics approvals beyond data protection are needed. Consult PRIO or the relevant authorities for guidance.
- ✓ Avoid plagiarism by always being clear about what your references are. As a general rule, it is better to include too many references in a document/ deliverable, than too have too few.

RECOMMENDATIONS FOR THE PROTECTION OF PRIVACY[43]

- ✓ Anonymize data as soon as possible
- ✓ Destroy data as soon as possible.
- ✓ Take care that data is not being used for any other purpose than it has been agreed to be used.
- ✓ Do not re-use data without written agreement of the owner.
- ✓ Make sure that participants in any research activity provide informed consent.
- ✓ Facilitate de-briefing for research activity participants[44].
- ✓ Process lawfully.
- ✓ Make sure to get informed consent.
- ✓ Process fairly.
- ✓ Collect data only for the purpose specified to the participants.
- ✓ Avoid collecting unnecessary data.
- ✓ Don't process data that is not up- to- date.
- ✓ Don't keep data longer than necessary.
- ✓ Process in accordance with individuals rights.
- ✓ Gather, process and store the data securely.
- ✓ Make sure not to transfer data outside the EEA- countries, without explicit permission.
- ✓ Anonymize data as soon as possible.
- ✓ Destroy data as soon as possible.
- ✓ Take care that data is not being used for any other purpose than it has been agreed to be used (mission creep).
- ✓ Do not re-use data without written agreement of the owner.
- ✓ Make sure that participants in any research activity provide informed consent.
- ✓ Only use technology for data recording, if absolutely necessary. Provide justification.
- ✓ Make the conduct of observation or recording of people very clear.
- ✓ Give anyone potentially affected by it the possibility to refuse from being observed or recorded.

[43] Derived from D95.21 (New: D14.21).
[44] Highlighted by the ESAB. See D95.12 (New: D14.12).

- ✓ Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research.
- ✓ Given the diverse range of national data protection and ethical guidelines of countries associated with DRIVER, it is important to adhere to the strictest, not the most lenient, rules and take those as the standard for all activities.

RECOMMENDATIONS FOR INCLUDING PARTICIPANTS IN THE RESEARCH:

- ✓ Identify as exactly as possible, what is being done in the experiments, and inform the participants as well as possible (without undermining the nature of the research activity or experiment).
- ✓ Obtain active full and real informed consent (more details in Chapter 7.2)
- ✓ If you need participants to play-act, aim at using professional volunteers, meaning pre-organized volunteers from e.g. the Red Cross or THW that have been properly educated and where insurance questions are clarified. Volunteers from these organizations have the added benefit or value of being aware of some procedures when it comes to handling a crisis during the experimentation, such as first aid.
- ✓ Proper insurance also needs to be in place, to safeguard against potential loss or injury. Should you not be able to use professional volunteers, but civilians, aim to invite civilians organized a sports club or similar, as these are likely to already have the necessary insurance in place through their organization[45].
- ✓ Ensure diversity among the participants in the sample. Practically, this means that extra attention needs to be given to creating a balance among the participants regarding gender, age and other demographic variables. This is important to ensure that the outputs of the research (the results) are generalizable and transferrable, and that they reflect a picture of reality that is as accurate as possible[46].

RECOMMENDATIONS FOR INFORMED CONSENT:

- ✓ Consent, as a legal basis, must be free, informed, and as specific as possible.
- ✓ The consent must be given unambiguously, without hesitation or doubt.
- ✓ For the collection and processing of sensitive data (cf. Chapter 4.1.1), explicit consent should be obtained, detailing exactly which data will be collected, how it will be stored, processed and deleted.
- ✓ The individual must be informed that the consent can be withdrawn at any time of the research (also after the informed consent form has been signed).

[45] However, these kinds of precautions do not formally fall under the scope of PRIO, but are the legal responsibility of the experiment- or task leader.

[46] For example, research show that Latinos are under-represented in biomedical research conducted in the United States. Ceballos, R.M, Knerr, S., Scott, M.A., Hohl, S.D., Malen, H., Thompson, B. (2014), Latino Beliefs about Biomedical Research Participation: A Qualitative Study on the US-Mexico Border. *Journal of Empirical Research on Human Research Ethics* 9:4.

- ✓ There must be active communication between the parties. This means that consent must never be inferred from a non-response to a communication, such as a letter [29].
- ✓ To ensure that consent is informed, consent must be given freely with sufficient information provided on all aspects of participation and data use.
- ✓ You should also give participants the possibility for "whistle blowing". For example, should a participant develop serious doubts regarding the research ethics of the project/ activity, the responsible researcher must ensure that he or she is allowed to present his or her worries to an independent consultative body, such as the DRIVER Ethical and Societal Advisory Board. This can happen through the Ethical Monitoring Report or by contacting task leader PRIO. It is furthermore important to make this option known in advance.
- ✓ It is very important that the researcher takes the time to listen to the participants concerns about what worries them in the activity/ experiment [30], but it is obviously difficult to pinpoint every potential harm, as participant could be upset by a certain question without the researcher having any chance to discover that in advance[47]. A best-practised research ethics is meant to avoid such incidents [30].
- ✓ Tailor the informed consent forms to the specific research context, stating the methods and sample, the nature of the data (personal, sensitive, level of detail), the format of the data (surveys, written, recordings) and the planned data processing. This will influence the type of consent and consent process used [30].
- ✓ Ask yourself whether informed consent is obtained from the subjects in a reasonable manner and whether it is evident that no dependency relations (e.g. between the individual and an employer) influence the subject's consent.

RECOMMENDATION FOR WHAT THE INFORMED CONSENT FORM SHOULD MINIMALLY INCLUDE:

- ✓ That participation is voluntary.
- ✓ That they may ask questions and receive understandable answers before making a decision about participation.
- ✓ The degree of risk and burden involved in participation.
- ✓ Who will benefit from participation?
- ✓ That they may withdraw themselves and their data at any time.
- ✓ That they are given a channel or a person to contact in case they have doubts about their role or the project.

[47] Although harm and the risk of inflicting harm is almost impossible to estimate or predict, harm could mean a number of things. In either case, it is subjective, for example it could mean that the participants are being embarrassed, distressed or anxious. This can for example happen if the participants feel that their values have not been respected.

- ✓ How their data will be collected, protected during the project and destroyed at the end.

11 General Recommendations for the DRIVER experiments[48],[49]

Below is a general checklist that will apply to most experiments. Details can be found in the lists in Chapter 10. Please note that such a list cannot be complete, because all experiments are different, and there might be fewer or additional considerations to take than what is listed below. However, this list can be used as an inspiration and as a starting point, and can be seen as a supplement to the list in Chapter 10. Furthermore, more detailed recommendations are presented in three separate lists: one for each state of the experiment process.

GENERAL RECOMMENDATIONS FOR ALL EXPERIMENTS

- ✓ Informed consent (see Chapter 7.2 in this deliverable for details) needs to be collected from all participants.
- ✓ In addition to the normal data protection approvals that are most likely needed for collecting data (including experiments), there might be a possibility that other ethics approvals are needed and that particular guidelines need to be followed, which are set out by national ethics bodies, *if the experiment has traits of the third kind of experiment described above*.
- ✓ Guidelines relevant if other ethics approval is needed concern the health, well-being and security of researchers and bystanders subject to the experiments and potential risks related to that.
- ✓ In some countries, regulations concerning the health, well-being and security of participants and bystanders are only handled on the level of guidelines; in others the conduction of an experiment requires an actual approval. Investigate what the case is for the relevant country.
- ✓ In most cases, the question of approval is dependent on the danger that the experiment participants are exposed to, and the proportionality of the risk it includes, for example when they act out specific situations that can put them in danger, psychologically or physically.

RECOMMENDATIONS FOR SETTING UP THE EXPERIMENT

- Clearly design and state the purpose, the content and the procedure for the experiment.
- Give enough information/ as much information as you can give
- Recruit participants that reflect the actual population that the experiment is meant to target

[48] Some of these recommendations are overlapping or similar to the ones in the checklist in Chapter 10.

[49] Although these lists aim at being a through guide on how to conduct research in an ethically sensible and good manner, PRIO does not claim that they are complete in all cases, or that there are not potential aspects missing that could be relevant in certain cases. However, the lists (also in Chapter 10) provide a general guide, and a starting point, both for adhering to central rules and regulations, as well as working as an awareness- raising exercise that could result in a partner realizing ethics issues where none were seen before.

- Ensure that the participant give their active and fully informed consent to participate (for best practice, not just signing a paper)
- If personal data is being collected, apply for and obtain data protection approval from the most local authority.
- Make sure that you have the practical formal approvals and procedures in place beforehand, such as flight permissions for UAV's, insurance arrangements, medical services on-site etc.[50].
- Inform all the participants of their rights and duties (to withdraw, to ask questions, to perform the agreed tasks etc.)

RECOMMENDATIONS FOR PERFORMING THE EXPERIMENT

- Only collect the kind of data that the participants have agreed to share.
- Make sure that all the participants have one dedicated contact person before/ during and after the experiment, and provide for a phone number and/ or email address where this person can be contacted for questions and concerns.
- Have a media- strategy ready, and a plan for how to include media on-site, taking the needs of the participant and the overall success of the experiment into account.
- Inform all participants as soon as possible of potential unforeseen issues and challenges that could affect them (e.g. if the experiments needs to go on for longer than planned,

RECOMMENDATIONS FOR EVALUATING/ CLOSING THE EXPERIMENT

- Was there a clear research question to be tested? If not, how could this be improved?
- Are the participants that took part in the experiment representative for their professional/ social/ ethnical groups?
- Is the main outcome of the experiment reliable? E.g. is it likely that another group of volunteers or unaffiliated volunteers could change the result significantly?
- Do not reuse collected personal data without permission from the data subjects (the participants)
- Offer de-briefs for the participants, if relevant and needed. As a general rule, offer de-briefs more willingly if vulnerable groups or minors etc. took part in the activity. The question of de-briefs should preferably be offered in writing, since some participants can potentially be uncomfortable with admitting to needing de-brief.
    - Remember also that de-brief can be a good occasion to sum up the day, and inform both participants (what happens to the data, photos, audio recording etc. of me) and the crisis managers (what did we learn, what went wrong, what are immediate reactions etc.) of the main points deriving from the experiment.

[50] However, these formal practicalities (beyond data protection and other ethical considerations) is not the role of PRIO to give guidance on, so it is merely mentioned here as an unavoidable step in the set-up and carrying out of an experiment.

- Do not share the data without permission from the data subjects (the participants who shared their personal data).
- Were outcomes measured by 'blinded' observers or were they objectively verified (e.g. quantitative measures recorded prospectively and independently) [33]?
- If there was a good reason not to disclose the full nature of the experiment (i.e. not giving the participant all information about the experiment or the particular scenario in advance), make sure that this is explained afterwards.
- Share and disseminate the results/ outputs of the experiment containing personal data according to the agreement with the participants. Do not share or reuse the data for other purposes that what was originally agreed upon with the participant beforehand. Otherwise, get written confirmation from the participants that it is ok to do so.

12 Conclusion

This revised version of D91.3 seeks to do two things: 1) provide the DRIVER partners with an easy-to-read, yet comprehensive, guide on how to go about in order to do their research in the best possible way in terms of research ethics. It does so by giving step-by-step guidance on how to get ethics approvals, and by providing templates and forms ready to use for seeking such approvals. In this way, it answers the needs of the partners as discovered through the ethical monitoring that the original SP9 has been doing already from M1 of the project, and as described by the partners directly in the first version of the Ethical Monitoring Report (D95.31) in M12. It does so while adhering completely to the description of the deliverable in the original DRIVER DoW, and addresses all questions and issues a)- h) on page 180. In addition, 2) it answer to the reviewers comments, and provides for more in-depth discussions and descriptions about the more subtle nuances in the realm of research ethics, and it exemplifies some such nuances by e.g. presenting some scenarios demonstrating that research ethics is not always a straightforward exercise and by providing some more granular chapters on relevant terminology and the conceptualization of research ethics.

The main purpose is nonetheless to provide an overview of the relevant ethical considerations that might appear during the DRIVER project. Some of the ethical issues are already relevant in the first 1,5 years of the project, some are rather likely to occur (such as difficulties in obtaining full and active informed consent), and some might occur later in the project (such as the need to re-evaluate the need for approvals beyond data protection in terms of e.g. the FD at the end of the project). However, this deliverable sets out the basic guidelines, and more detailed guidelines in particular areas that are needed for conducting research in a good ethical manner, and it serves also as the starting point for discussions and awareness-raising with and among the DRIVER partners who are hosting and performing experiments. It does so by inspiring thinking about the perhaps “less-practical” and more “fluid” considerations and challenging scenarios (not in terms of the DRIVR scenarios, but of actual potentialities) that not all DRIVER partners have been aware of before, or that they haven’t been exposed to in previous projects.

In sum, DRIVER, as a large demonstration project, has the potential to pose new ethics issues because of its complex nature, many (combined) solutions and large experiments. While this deliverable gives both a more general introduction, as well as very clear practical instructions on how to decide if you need approval and how to get it, the annual Ethical Monitoring Reports (version 1 was ready in M12, April 2015) is dedicated to addressing particular problems and challenges that appear throughout the year and the rest of the project. Nonetheless, although the need for additional clarifications may occur as the project progresses, all recommendations given in this deliverable are, and will continue to be, valid for ensuring ethical research throughout the duration of the project.

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Annex

1.1 Informed Consent Form template

General information about the research project (INSERT A TITLE FOR THE RESEARCH YOU WILL CONDUCT FOR DRIVER)

The **DRIVER** project, Driving Innovation in Crisis Management for European Resilience, gathers the expertise of 37 organisations, who will jointly develop solutions for improved crisis management. A distributed pan-European test-bed will be built for experimentation and testing and the most useful new solutions will be collected in a comprehensive Crisis Management portfolio at the end of the project. Building upon the findings of previous research projects, DRIVER's ultimate goal is to enhance European resilience in the face of crisis situations and ascertain sustainable innovation in Crisis Management also after the end of the project.

Description of Research

The research under the lead of (ADD NAME OF LEAD RESEARCHER & LEAD INSTITUTION) focuses on (NAME MAIN AIM OF THE TASK/S) and is embedded in the DRIVER project.

DESCRIBE IN 5 SENTENCES:

- WHAT YOU DO IN THE PLANNED RESEARCH (IF YOU HAVE, ADD A RESEARCH QUESTION)
- WHY YOU DO IT, WHAT FOR
- HOW YOU DO IT
- HOW THE DATA WILL FEED INTO THE DRIVER PROJECT

Selection of participants and treatment of data

DESCRIBE IN HALF A PAGE:

- YOUR SAMPLE (HOW MANY PARTICIPANTS)
- ON WHAT BASIS YOU CHOSE THE PARTICIPANTS, WHY
- HOW YOU CONTACTED THE PARTICIPANTS
- WHAT EXACTLY YOU WANT THE PARTICIPANTS TO DO/ANSWER/TALK ABOUT
- WHAT KIND OF DATA THIS RESEARCH WILL PRODUCE
- WHETHER AND HOW THE DATA WILL BE RECORDED, TRANSCRIBED, ENCRYPTED OR ANONYMIZED
- HOW THE DATA WILL BE STORED, WHERE AND HOW LONG FOR
- HOW THE DATA WILL BE PROCESSED, ANALYZED, WHO WILL HAVE ACCESS TO AND RESPONSIBILITY FOR IT

Your participation

Your participation is integral to the project and will contribute to the quality and novelty of research on crisis management and resilience. Participation in the project means that you will

be asked to take part in (DESCRIBE 4-5 SENTENCES WHAT THE DESIGN OF YOUR INTERVIEW/FOCUS GROUP ETC. IS, WHAT GENERAL QUESTIONS WILL BE ASKED OR REQUIREMENTS NEED TO BE FULFILLED). Participation in the interview is entirely voluntary. You will not have to share information that you consider private. Your participation in the project can be withdrawn at any time without further notice. In that case your data will be deleted instantly. We point out that the complete withdrawal of your data may not be possible after the point in time data has been anonymized, clustered or generalized. (INDICATE WHEN IN THE PROCESS THIS MAY HAPPEN).

- WHERE APPLICABLE ADD: Since you will be asked to (EXPLAIN POTENTIALLY UNCOMFORTABLE QUESTIONS ETC.), it is important to ensure that you are comfortable sharing this kind of information.

- ADD A SENTENCE ON WHETHER DATA WILL BE SHARED. IF SO IN WHAT FORM AND WITH WHOM.

The research commenced in May 2014 and comes to an end latest in (ADD END DATE).

- DESCRIBE IN 1 SENTENCE HOW, WHERE, AND BY WHOM THE DATA WILL BE STORED, FOR HOW LONG, HOW IT WILL BE PROCESSED AND WHEN IT WILL BE DESTROYED.

- PROCESSING: DESCRIBE IN 2-3 SENTENCES WHAT INFORMATION YOU WILL DRAW OUT FROM THE DATA AND HOW (GROUPING ANSWERS, MAKING CLUSTERS, MAKE GENERAL RECOMMENDATIONS ETC.)

(LEAD RESEARCHER) will publish the results in such a way that individual views and arguments can never identify participants. The limited personal information gathered will be treated confidentially and (LEAD RESEARCHER) will duly respect this. (DESCRIBE WHO HAS ACCESS TO DATA.)

(LEAD INSTITUTION'S) part of the project is authorized by the (ADD YOUR DATA PROTECTION AUTHORITY, ONCE YOU HAVE APPROVAL).

If you allow (NAME OF LEAD INSTITUTION) to use your data in the project, please express your Consent in written form by signing below.

Your name in block letters:

Participant's Date & Signature:

If you have any questions please don`t hesitate to contact (NAME OF LEAD RESEARCHER). Should you have any complaints about the way the research is carried out you can contact (NAME) at (DATA AUTHORITY).

Kind regards,

(NAME, SIGNATURE LEAD RESEARCHER)

(ADD CONTACT DETAILS OF LEAD RESEARCHER)

1.2 Template for Research Ethics Approval Application

Application for Research Ethics Approval

➔ **NOTE: INSERT A TITLE FOR THE RESEARCH YOU WILL CONDUCT FOR DRIVER**

Research conducted within the FP7-funded DRIVER project

« Driving Innovation in Crisis Management for European Resilience »

To be Submitted to ➔ NOTE: FILL OUT RESPONSIBLE INSTITUTION

➔ NOTE: Please fill out the points below. This template is a guideline. Please ensure that you are not obliged to follow particular national guidelines for application provided by your local Data Protection Authority.

All categories and questions below are either directly quoted from or inspired by the **Norwegian Social Science Data Services** (NSD) *Notification Form*. Available at : http://www.nsd.uib.no/

General Information

- *Responsible institution*
- *Project leader*
- *Objective of project*
- *Other involved institutions*
- *Who of the involved institutions will have data access?*

Sample

- *Sample (number of participants, age, location of participants)*
- *Is the data your own or are you getting it from a different institution (like the Red Cross, the police, administrative files, etc.)*
    - *If yes, please ensure whether or not the institution that provides it to you needs approval from within their institution.*
    - *If no, please proceed below.*
- *How are participants/interviewees recruited? (How will selection take place and how will they be contacted)*
- *Will any legal adult with reduced capacity to legal consent be recruited?*

Data Collection

- How will the data be collected? Please expand on the selected method.
    - Questionnaire
    - Personal interview
    - Group interview
    - Observation

- Psychological tests
- Medical tests
- Records
- Registers

Data Content

- What is the content of the data?
- Will directly identifying data be collected (social security number, name, date of birth, email, phone number etc.)? Please specify.
- Will indirectly identifying data be collected (it is possible to deduct from background information who the person is likely to be. Background information can be age, gender, part of a specific group etc.). Please specify.
- Will sensitive information about a person be collected? ("*Sensitive personal data* includes any personal data consisting of the following information: race or ethnic origin; political opinions; religious or other beliefs; trade union membership; health; sexuality; or alleged or actual criminality."[51])
- Will information about third persons be collected (secondary information from which it is possible to deduct the identity of a third person)? If so, in what way will the third person be informed?

Informed Consent

- Specify how participants will be informed about the project (verbal, written, will not be informed).
- Specify how participants will give their consent (verbal, written, not at all).

Information Security

- Is indirectly identifying information replaced by a reference number which refers to a separate list of names?
- How will the list of names be stored, who will have access to it?
- Is directly identifying information registered together with the other data? If yes, please explain why.
- Is indirectly identifying information registered or stored?
- How is the data registered, saved and processed?
- Are audio-, video-recordings and /or photographs saved and/or processed on a computer?
- How is the data safeguarded from unauthorized access?
- Do you use a portable storage device? If so, why and how will it be used?
- Who will have access to the data?
- Will personal data be transferred through the internet? If so, please specify information.
- Will personal data be transferred to anyone outside the project team? If yes, please specify.

[51] University of Oxford (2012) "Data Protection and Research" Legal Services Briefing Note, p.4

- Will data be gathered or processed by an external processor? If so, please specify.

Approval by Other Regulating Bodies

- Will your project require a dispensation from the duty of confidentiality in order to gain access to the data? (e.g. data from public institutions) If so, you must apply for a dispensation from the duty of confidentiality at the relevant government departments.

Duration of the Project

- How long will the project last?
- What will happen to the data when the project is completed?
- Where and for how long will the data be filed?
- Will the data be filed with personal identification? If so, why?
- How will the project be financed?
- Any other relevant information?