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

D130.42 Ethical Monitoring Report 2

Document Identification	
Due Date	30/04/2016
Submission Date	30/04/2016
Status	Final
Version	1.0

Related SP / WP	SP1/ WP130	Document Reference	D130.42
Related Deliverable(s)		Dissemination Level	PU
Lead Participant	PRIO	Lead Author	Stine Bergersen (PRIO)
Contributors	FOI, FHG, POLE, ATOS, ECORYS, MSB, JRC, FHG-IAO, ARC, DRC, ARMINES, POLE, Q4PR, FRQ, AIT, TCS, DLR, GMV, ITTI, EDI, MDA, THG, ARTTIC, TNO, USTUTT	Reviewers	Helene Ingierd (External Expert on Research Ethics, Director of NENT & member of the DRIVER Ethical and Societal Advisory Board) Katerina Hadjimatheou (University of Warwick & member of the DRIVER Ethical and Societal Advisory Board)

Keywords:
Research ethics, ethical approvals, ethical considerations, ethics monitoring, DRIVER experiments, human subjects, privacy, data protection

This document is issued within the frame and for the purpose of the *DRIVER* project. This project has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under Grant Agreement No. 607798

Document Information

List of Contributors	
Name	Partner
Stine Bergersen	PRIO
Input via questionnaire distributed by PRIO	FOI, FHG, POLE, ATOS, ECORYS, MSB, JRC, FHG-IAO, ARC, DRC, ARMINES, POLE, Q4PR, FRQ, AIT, TCS, DLR, GMV, ITTI, EDI, MDA, THG, ARTTIC, TNO, USTUTT

Document History			
Version	Date	Change editors	Changes
0.1	15.04.2016	Stine Bergersen, PRIO	Draft ready for review
0.2	25.04.2016	Stine Bergersen, PRIO	Reviewed by Helene Ingierd (member of the DRIVER Ethical and Societal Advisory Board)
0.3	28.04.2016	Stine Bergersen, PRIO	Reviewed by Katerina Hadjimatheou (member of the DRIVER Ethical and Societal Advisory Board)
0.4	29.04.2016	Stine Bergersen, PRIO	Comments from both reviewers incorporated, final version sent to Atos for quality check.
1.0	30.04.2016	Charles Bastos, ATOS	Final Quality Check performed and version ready to be submitted.

Table of Contents

List of Tables

List of Figures

List of Acronyms

Abbreviation / acronym	Description
CM	Crisis management
D	Deliverable
DoW	Description of Work
DPA	Data Protection Authority
ESAB	Ethical and Societal Advisory Board
FD	Final Demo
IT	Information Technology
JE 1 & 2	Joint Experiments 1 & 2
NENT	The Norwegian National Committee for Research Ethics in Science and Technology
SC 15	Special Clause 15 in the Ethical Guidelines of the FP7 agreements
SE 1 & 2	Subproject Experiments
SP	Sub project
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.

DRIVER is a 54 month duration project co-funded by the European Commission Seventh Framework Programme (FP7/2007-2013) under grant agreement no. 607798.

Executive Summary

This document is the second annual Ethical Monitoring Report in DRIVER. The aim of the report is to monitor, i.e. document and address issues relating to research ethics in the project.

In the original DRIVER project structure, this task was part of subproject 9 (WP95), where PRIO was in charge of ethical monitoring of the project through these annual ethical monitoring reports. This task is now moved to SP1/ WP130, but is still led by PRIO. This current report is the second of the annual ethical monitoring reports (first report submitted in M12 as D95.31), and it is submitted under the new project structure. However, the content and setup of the report (and the task as such) follows a similar structure as the original. The general idea behind the report is to document and address key research ethics issues in the second year of DRIVER, and to repeat and refine some core points from previous deliverables; both to clarify some particularly important points regarding research ethics, but also to update and specify previously given guidelines. It does so by taking up the most pressing or challenging issues relating to research ethics, as seen by WP130 leader PRIO, and as experienced by the DRIVER consortium. The latter information is derived from Ethical Monitoring Questionnaires (hereinafter referred to as the "questionnaire") sent out to 25 of the project partners as per DoW. The report summarizes the main deliverables on research ethics relevant for the reporting period, which at this point are the resubmissions of D91.3 ("Ethical Procedures, Risks and Safeguards") and D95.21 ("Planning for Ethical Approvals"). In addition, this report also reflects the insights and issues from the second DRIVER Ethical and Societal Advisory Board (ESAB) meeting in September 2015 more substantially than the last report, with the ambition to further strengthen the integration of the ESAB into the project. In this way, the most relevant information is consolidated in this report that serves as an update on the work on research ethics in DRIVER.

Similar to the first Ethical Monitoring Report (D95.31), the input to this report is mainly derived from five different sources: 1) questionnaires filled out by 25 DRIVER partners required to give input as per the new DRIVER DoW. The returned questionnaires cover all subprojects, and all roles within the project (researchers, test-bed owners, experiment leaders etc.), 2) Minutes and reflections from the second DRIVER Ethical and Societal Advisory Board meeting, which held its second meeting of the project at PRIO premises in November 2015. 3) Interaction in relation to the DRIVER meeting week in Lund November 2015. 4) Issues of ethical concerns which has become apparent to PRIO as former SP9 leader (in particular as leader of WP91 "Coordination and Conceptualization of Independent monitoring" and WP95 "Ethical and Societal Advisory Board"), and now as new leader of WP130. 5) The deliverable finally also repeats and refines some core points from previous deliverables.

One of the main conclusions of this second report is that although there might be some challenges that need to be solved in particular cases, no activities or experiments that include major (unacceptable) negative implications in terms of research ethics are foreseen at this point. However, PRIO would again want to remind the consortium of the importance of having the appropriate ethical

approvals in place, and of the fact that this is the responsibility of the relevant partners, not of PRIO. This information (and other information in this report) is repeated and iterated due to the fact that new activities involving new partners and constellations of partners and activities have started or taken place in the reporting period, and this makes a reminder or a repetition necessary.

1 Introduction

This report is the second out of four Ethical Monitoring Reports (due in M12 (submitted), M24, M36 & M48 of the project), and it follows a similar structure as the first Ethical Monitoring Report, D95.31, which was submitted in M12. The report contains some repeated material from the first report, due to the fact that new partners and new constellations of partners have undertaken or will undertake new activities within or following the reporting period. For example, SP6 was due to start only in M11 (April 2015). In this sense, the information from the first report is still valid for most partners, hence the key issues and topics are addressed in this report as well. It should also be mentioned, that in the reporting period, the DRIVER partners were to a large extent concerned with the restructuring of the project, and thus some activities were put on hold. Only the most crucial issues and challenges are reiterated in this second version of the report.

Since the first report was finalized, a few deliverables concerning research ethics have been submitted. In general, the main task on research ethics was the resubmission of D91.3, which is a thoroughly revised document, following the comments from the reviewers. In particular, the document more clearly underlines 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 resubmission of D91.3 was done in accordance with current needs and issues in DRIVER, and should be seen as a result also of the issues documented in this monitoring report.

In addition, D95.21 was resubmitted. This deliverable contains the plan for the monitoring of ethics approvals. As the feedback from the Ethical Monitoring Questionnaires (hereinafter referred to as the *questionnaire*) sent out to solicit feedback to this deliverable also show, a large proportion of the consortium partners report that they are not experiencing any major issues that are expected to have severe implications in terms of research ethics. While this is the case, there is also good reason for the continuing monitoring of the project activities, especially due to the fact that the Joint Experiments (JE1 & JE2), as well as the Final Demo (FD) are still pending. It should also be acknowledged that there is a certain margin for error concerning that way the information to this deliverable is solicited, which makes the continuous follow-up in close collaboration between PRIO and the relevant partners, important. While the use of questionnaires is practical for soliciting feedback from 25 partners, PRIO has no way of validating the information, or ensuring that as complete answers as possible are given. However, the report is, based in particular also on PRIO´s effort in T130.2, a realistic indication of what kind of issues and challenges that exists and are expected to be of relevance, for the DRIVER partners in the future (beyond M24). In addition, it should be mentioned that a side-effect with using a questionnaire (in addition to providing actual input to this report) is also to act as a reminder for the partners, and perhaps also raise awareness of what key ethical issues could look like for future (beyond M24) experiments and activities in the

project. This is particularly relevant for those partners who do not have any or extensive experience with research ethics in their daily work.

1.1 The Fundamental Importance of Research Ethics

A basic definition of research ethics also implicitly explains why it is so important; the application of moral rules and professional codes of conduct to the collection, analysis, reporting, and publication of information about research subjects, in particular active acceptance of subjects' right to privacy, confidentiality, and informed consent [1]. While this slightly restrictive and more practically oriented definition is cited from the DRIVER Terminology, in the even wider sense, research ethics also includes the responsibility for the wider societal impacts of the research[1]. A more extensive definition is a broad set of standards, values and institutional arrangements that contribute to constituting and regulating research activities. These include the duty of honesty in research as well as responsibility to colleagues, other people, animals, the environment and society in the widest sense [2]. The main concern of research ethics in DRIVER is not only to conform to given legal and moral codes, but also to enhance the legitimacy and scientific quality of the project. The basic guidelines for fulfilling the most common research ethics obligations can be found in D91.3 (resubmitted in M22).

The key ethical principles relevant for DRIVER are described in part B4 of the DRIVER DoW, and issues involved will be documented and addressed in the periodic Ethical Monitoring Reports. The basic premise for these reports, as well as the need for attentiveness with regards to research ethics in the first place, is the fact that research ethics fundamentally refers to the need to govern the impact (both positive and negative) that research can have on the society. The formal side of research ethics is about finding good ways to incorporate and integrate rules, regulations and “best practises” [6] for how to include these conditions in the very fabric of the research activities on a fundamental level. In terms of application, research ethics concerns everyone involved in the research activity; e.g. funders, researchers, human research subjects and bystanders.

The DRIVER project involves the collection, processing and storage of data derived from individuals, both from members of the DRIVER consortium and individuals that are not formally part of the project. At the very core of research ethics are rules and guidelines for the participation of human subjects in research activities, which refer to the standard European Commission research ethics. The

[1] In DRIVER, the task of monitoring and giving guidance with regards to research ethics is separated from the task of societal impact. Both of these tasks are led by PRIO, and it is clear that there are indeed overlaps between the two. For example, carrying out research in an unethical manner will for sure have societal impacts, and similarly, that an activity has societal impact, e.g. it fosters trust, can feed back and influence the practical implementation of research ethics guidelines. Nonetheless, in DRIVER, these two tasks are separated, also because of the outputs of the tasks. While the research ethics task (producing guidelines, advising the partners, monitoring ethics approvals etc.) is applied to DRIVER and is a continuous effort in the project, the societal impact task will ultimately produce a consolidated approach to doing societal impact assessments in the crisis management context, and will live on as one outcome of DRIVER (while not explicitly linked to its concrete activities).

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 [6] must be strictly upheld at all levels when addressing ethical questions and issues within DRIVER.

Failure to uphold principles for ethical research, such as obtaining the appropriate informed consent- and data protection approvals within the set timeframe, is not only exercising poor research ethics, but it is also a breach of the contractual agreement through the Special Clause 15.

1.2 Sources of Information for the Ethical Monitoring Report

As with the first Ethical Monitoring Report (D95.31), the issues concerning research ethics described in this deliverable are issues that have been raised and discovered through various channels and mechanisms within the second year of the project. The information that forms the basis for this deliverable, as well as the first report, mainly derives from five different sources that are further described below:

ETHICAL MONITORING QUESTIONNAIRES FROM ALL SUBPROJECTS

1) The information is mainly derived from the partners tasked in the new DoW to contribute with input to this deliverable. Here, issues that are of particular relevance to the different partners have been raised, and some will be addressed specifically in the following. Partners required to give input to this document were: FOI, FHG-INT, POLE, ATOS, ECORYS, MSB, JRC, FHG-IAO, ARC, DRC, ARMINES, Q4PR, FRQ, AIT, TCS, DLR, GMV, ITTI, EDI, MDA, THG, PSCE, ARTTIC & TNO[2]. The respondents cover all categories of roles within DRIVER, including researchers, beneficiaries [6], solution providers, test-bed owners etc. The feedback from the 25 partners was solicited through the use of a questionnaire[3], which was sent out to all partners on the 18th & 19th of March 2016. At least one filled- out questionnaire per partner was returned to PRIO[4]. All the questionnaires are stored digitally and physically with PRIO and can be retrieved by the REA or the project leadership upon request. The questionnaire (annexed to this report) covers all the major ethics issues in part B4 of the DRIVER DoW, and contained questions on human subjects in research, ethical approvals, the interaction with SP9 and later WP130, potential topics for the DRIVER Societal and Ethical Advisory Board, as well as other ethical issues. In short, the questionnaire provides every partner receiving it with

[2] The questionnaire from PSCE has not been returned to PRIO and is not included in this draft. However, USTUTT provided a questionnaire, making the number of respondents the same as in D95.31.

[3] It must be noted, however, that while the partners listed in the DoW are mostly represented in this report, other partner's issues and experiences are partly represented through the other sources mentioned below.

the opportunity to raise any issue regarding research ethics. The information from the questionnaires has been anonymized, and this report contains no mentioning of particular individuals or organisations. Although not every issue can be described in detail in this deliverable (also because many of the DRIVER activities are still pending, and detailed information cannot be given at this point), the most prominent and overarching issues and challenges are documented and addressed here. Similar to the first report, the information from the questionnaires are for the most part not addressed in particular chapters, but rather embedded throughout the report.

THE DRIVER ETHICAL AND SOCIETAL ADVISORY BOARD

2) The information about research ethics is also derived from the DRIVER Ethical and Societal Advisory Board[5], which held its second meeting at PRIO premises in Oslo, in September 2015. The second meeting's purpose was to update the Board on the status of the project, in terms of the effort on research ethics, but also to introduce the concept of Societal Impact Assessments (SIA) [6]. Feedback on particular questions relating to ethical issues from year 1 of DRIVER was solicited (i.e. the first Ethical Monitoring Report-D95.31 & the general ethical monitoring process). For both the first and second meeting, the ESAB gave a lot of valuable feedback and contributed to useful discussions. In the second meeting, the ESAB was reintroduced to and updated on the project, and some particular ethics issues and questions that had appeared since the last meeting were raised and discussed. Some of the key issues are reflected in this deliverable, but the details can be found in D95.12, which contains the meeting minutes, as well as the PowerPoint presentations given at the meeting. The integration of the discussions from this second ESAB meeting is intended also to underline the role of the Board in the project, and to highlight how they are actually involved in the research ethics activities in between the ESAB meetings and throughout the year. In more practical terms, the information regarding the topics discussed at the second ESAB meeting also gives valuable information to PRIO on how to deal with concrete issues and challenges.

DRIVER MEETING WEEK IN LUND, SWEDEN 2015

3) The second big DRIVER meeting week gathered the consortium, and drew together partners with different roles in the project. These big meetings often turn out to be an occasion for partners to approach PRIO directly, to ask questions relating to ethics. During the second big meeting week in Lund in November 2015, PRIO gave a presentation for the DRIVER General Assembly on the work on Societal Impact Assessments (SIA) [6] for the crisis management context, which PRIO is tasked with (now

[5] The Ethical and Societal Advisory Board (ESAB) is an independent committee that advises DRIVER and in specific WP16 about ethical challenges and societal aspects of crisis management and research done throughout the project. The ESAB met for the first time in Brussels on the 4th of December 2014, and for the second time in September 2015.

in WP840). Although the session was focused on Societal Impact Assessments (contrary to the research ethics workshop PRIO gave during the first DRIVER meeting week in Ispra in Italy in February 2015), the feedback and questions before, during and after the presentation indicated that there was (still) some confusion with regards to the distinction between the concept of research ethics and the concept of societal impact in DRIVER. Therefore, in this report, PRIO explains what actions have been taken to counteract and clarify this misunderstanding[6]. In short, the restructuring of the project, which effectively meant splitting the old SP9 in half, and moving the activities regarding research ethics to SP1 and the societal impact assessment activities to the new SP8 on "Assessment & Innovation", is expected to reduce the risk for misunderstandings in terms of these two roles. Also, the effort that has been made in the past two years, to guide and advise the partners on research ethics is expected to become less pragmatic and general, and more applied to particular cases and concrete questions, in the coming years. In other words, as the basic information and guidelines have now been provided, the interaction with the partners in terms of research ethics is most likely to concern particular issues for the (joint) experiments and the Final Demo (FD).

4) Also, within WP130 (ex- WP95) lies the task of monitoring the process and need for ethical approvals for the DRIVER partners. Experience from this task is also part of the information basis for this report. Throughout this task, it has become clear to PRIO that although a lot of attention and effort has already been put into this task in the past, it is very likely that still some new questions will need clarification in the future (beyond M24), and that there will still be a need to repeat core issues. This is expected especially for two reasons; 1) that new partners are becoming involved in the research activities, and 2) that the experimentation activities are becoming increasingly more complex in their nature, particularly with the combining of solutions to be tested in the two Joint Experiments (JE1 & JE2). For these reasons, this deliverable also seeks to document and address some of the most frequently raised issues derived e.g. from bilateral interaction between the task leader and the DRIVER partners. Reiterating and reflecting a bit upon these issues is intended to be useful for partners that might not have started their activities or needed to submit e.g. data protection approvals yet at this point in time (M24).

5) Finally, parts of the content of this deliverable are simply iterations and further refinements of issues from the previously submitted deliverables D91.3 and D95.21. The first Ethical Monitoring Report (D95.31) iterated the most basic information on e.g. Special Clause 15 and how to decide if data protection approval [6] is needed for an activity. Given the fact that this information is still relevant for the partners, also since

[6] While PRIO acknowledges that there is in reality some degree of an overlap between the two concepts (e.g. should research ethics be completely overlooked, this might have serious societal impacts), the approach to this in DRIVER is that the two should be regarded separately, i.e. by now in the new structure of DRIVER to address Societal Impact through WP840 and research ethics through WP130.

new partners have started with new activities since the last report, some information of this kind is reiterated in this document as well. This makes the row of Ethical Monitoring Reports into increasingly refined documents, that are always updated according to the most current and pressing needs in the project, while based on key principles for research ethics. However, it is also necessary to emphasize that the two main documents for advising the project partners about research ethics are D91.3- "Ethical procedures, Risks and Safeguards" (which is the main guiding document for how to practically deal with research ethics) and D95.21- "Planning for Ethical Approvals" (which contains more administrational information, i.e. the calendar[7] for who will likely need approval at which point in time throughout the project). Both of these deliverables were rejected in the Year 1 review, but have been revised, updated and resubmitted, and are available in final versions in the DRIVER Space and upon request.

1.3 Structure of the Deliverable

The structure of this deliverable is as following. The remainder of Chapter 1 introduces the fundamental importance of research ethics, explains the sources of information for this report, and the relation with the other deliverables on ethical issues (in particular the two resubmitted deliverables D95.21 "Planning for the Ethical Approvals" and D91.3 "Ethical procedures, risks and safeguards"), the impact of the Year 1 review and the restructuring process on this deliverables, and the scope and limitations of this second Ethical Monitoring Report. Chapter 2 addresses and documents data protection & privacy issues, e.g. in terms of interactions between DRIVER partners and the Data Protection Authorities. Chapter 3 described the inclusion of human participants in DRIVER, such as issues of informed consent and the inclusion of vulnerable groups. Chapter 4 describes the role and work of the new WP130- "Research Ethics, Scientific support, IPR & legal issues Y2-5» within DRIVER, what is working and what can be improved, and is largely based on the feedback from the ethical monitoring questionnaires. 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. Chapter 6 concludes the report. Templates for informed consent and for general research ethics applications can be found in annex, as well as the Ethical Monitoring Questionnaire.

[7] It should be noted that once the new DRIVER DoW has been approved, PRIO will prepare a revised calendar for the approvals needed for the rest of the project that will be the basis for the collection of approvals through T130.2. The next deliverable collecting these approvals is due in October 2016 (M30).

1.4 Impact of the Year 1 Review and the Restructuring of DRIVER

The first Ethical Monitoring Report (D95.31) was accepted following the Year 1 review. The reviewers commented that it was a "detailed and well considered exploration of the implementation of the ethical process in DRIVER", although at times "a bit idealistic". While it is certain that practicalities will at times hamper the potential for the ideal implementation of procedures and safeguards for research ethics, this second version of the report nonetheless has as its basic aim to explore and partly detail what is considered "best practise" [6] for research ethics, acknowledging that DRIVER strives for upholding nothing but the highest standards in this regard. Taking the Year 1 Review feedback into account, this deliverable therefore largely follows the same structure as the first version, and is based on the same main sources of knowledge.

Since the first Ethical Monitoring Report (D95.31) was submitted, the project has undergone a thorough restructuring. This does not concern the *content* of the tasks on research ethics led by PRIO that were originally located in WP91 and WP95, but it concerns the way in which these tasks are *structured*. In short, WP95 and T91.3 (where the work on research ethics previously was handled) have now been moved and merged into one new work package. This new work package (WP130) is now managed under SP1. Through this merging, and by being part of the Project Management subproject, the focus on research ethics in DRIVER as a crucial and mandatory consideration is further strengthened and centralized, and it is now easier for the DRIVER partners to know where the research ethics component of the project is located.

1.5 The Resubmission of D95.21 and D91.3

As mentioned, the two deliverables that set up the process of ethics monitoring for the project were rejected in the Year 1 Review. Since these are crucial for the work PRIO does in terms of research ethics, some further explanations with regards to these are made in the following. While D91.3 was the main document for giving guidelines on how to deal with research ethics, D95.21 set up the calendar and the more administrational side of the monitoring of research ethics by PRIO. This short section of the Ethical Monitoring Report is intended to summarize in a few words how these two deliverables were revised and resubmitted, and explain how they were rewritten to answer better to the current needs in the project at the time of resubmission. The reason that this chapter is included in this report is to explain in one consolidated chapter what the main criticisms were, and how these were addressed by PRIO in the resubmission (and in the overall restructuring). This is important to include because it structures the work ahead for PRIO, it represents major efforts by PRIO in terms of research ethics for the reporting period, and it also indicates what the main challenges in terms of research ethics as seen by the reviewers were in Year 1 of the project.

With regards to D95.21 "Planning for Ethical Approvals" this was a document described in the original DoW as "a detailed planning of ethical approvals required per task/ activity". The resubmission focused on the distinction between *planning* for the monitoring of the approvals and

the detailed *guidelines* for research ethics and principles. D95.21 is an administrative deliverable with templates that is offered to the consortium partners in need of them, and a schedule for activities and their likely need for approval. The main comments from the reviewers were that the deliverable does not reflect that many of the partners are not researchers, and therefor may not so habitually think about ethics in research. Answering to this, PRIO made clearer the distinction between D95.21 and D91.3 in the resubmission and revising of both. The paragraph below (quoted from the "Rejected Efforts Template" that was submitted together with the resubmission of D95.21) explains this.

> *D95.21 has an introduction that introduces research ethics briefly, however, it is outside the scope of the deliverable to provide for an in-depth introduction to research ethics, since it is merely an administrative deliverable. However, the related document D91.3 has been re-written in order to provide all the partners in DRIVER with clear, step-by-step guides and recommendation lists, for obtaining ethical approvals. This deliverable speaks to all partners (also those who are not used to dealing with research ethics), but also provides more detailed examples and instructions for particular cases. This deliverable is the main source of information and guidance on research ethics, while D95.21 provides the set-up and the plan for how this process practically will be carried out by PRIO. Instead of adding more information to D95.21 we decided to rather keep a clear division between D95.21 as an administrative deliverable with templates and a schedule, and D91.3 that collects all information about research ethics and introduces research ethics to the consortium.*

Answering to the comments from the rejection of D91.3, PRIO identified five main topics and issues in the comments from the reviewers. These are summarized below (the five issues below are quoted from the "Rejected Efforts Template" that was submitted together with the resubmission of D91.3).

1) ***"Too general and straightforward"***
   - *Since it is clear to PRIO (through e.g. D95.31 and T95.2) that many partners still need "straightforward" and rather general guidelines, the resubmission on the one side: 1) expands and details the general introductory guidelines for responsible research ethics (mainly Chapter 4 & 5), and on the other side 2) goes more into depth about the underlying assumptions and definitions related to such concepts as data protection, transparency and accountability (Chapter 3). It also more clearly and explicitly links and refers to the other deliverables produced within the old SP9, where some of the issues that the reviewers requested are addressed.*

2) ***"Lack of authorities sources"***
   - *Many authorities sources has been added to the revised deliverable, e.g. policy documents, academic literature, legal texts and legislations, EU law, national guidelines, 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"***

- *A chapter is added where the concept and foundation of research ethics, and why it is important, is discussed. Furthermore, key terminology and concepts are presented, and the question of research ethics as a question of methodology is discussed. Examples of ethical dilemmas in research are given, to further illustrate subtle issues of research ethics. 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.*

4) ***"Process for ethical challenges"***

- *The deliverable has been updated with a clearer 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, where the relation between DRIVER and the ESAB is addressed, and the purpose of the Ethical Monitoring Reports is described.*

5) ***"Unclear purpose of the deliverable"***

- *The structure of the deliverable has been strengthened to more clearly follow the structure as indicated in the original DRIVER DoW. The deliverable answers all points a) – h) indicated in the DoW. 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". 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.*

In sum, the resubmissions have made clearer the distinction between the deliverable that provides guidelines for research ethics, and the deliverable that administrated the process for how to fulfil or adhere to the recommended guidelines. In D95.21 (this task is now part of WP130), PRIO indicate which tasks need approval and when, and in D91.3, the procedures, risk and safeguards for getting these approvals and for maintaining high ethical standards are given. In addition, in what is now T130.2, these approvals are collected and stored per task by PRIO. In addition, through the Ethical Monitoring Reports in T130.4 (task is now part of WP130), 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 T130.1 (task is now part of WP130).

1.1 The Scope and Limitations of the DRIVER Ethical Monitoring Report

As stated also in the first Ethical Monitoring Report (D95.31), ideally, such a report would allow for a comprehensive analysis of all the various ethical issues that pertains to DRIVER at this point. However, due to constraints in terms of effort, and varying level of detail in the feedback from the

questionnaires (partly explained by relevant activities starting at a later point in the project, after M24), some key issues have been selected as the basis for this report. This does not mean that WP130 is not engaging with other ethical issues that are being raised and set forth to WP130, as these kinds of interactions are happening in parallel and in different channels (in particular through T130.2). The purpose of this report is to identify and address *key* ethical issues, and this includes making a distinction between smaller issues of anticipated less importance that are (or have been) easily solved between PRIO and the relevant partner through T130.2 (the Ethical Approval-task), and the more overarching, general and fundamental issues which are or will most likely be of relevance to more or less the DRIVER consortium as a whole, or that poses the more significant risks to the project should they not be addressed. The deliverable does not aim at summarizing all ethical issues from the second year, but rather to focus on the state of the project at this point, and to tailor the relevant information that PRIO will be providing for the next reporting period thereafter. The next chapter concerns the fundamental research ethics issues relating to data protection and privacy, topics that many of the DRIVER consortium members come into contact with, directly or indirectly.

2 Privacy and Data Protection

The single most important issue for the research activity within the DRIVER project is still related to privacy and data protection, and how to safeguard the former via implementing the latter. The most likely approvals that will be needed, as well as the most relevant daily management issues from PRIO's side has to do with these concepts, and it is likely that this is something that most of the partners in DRIVER will have to relate to at one point or another. The notion of privacy has a role to play within several basic ethical principles concerning people in research, e.g. with regards to respect for individuals (both the researcher and the people included in the activity), the potential for good/bad consequences of the activity on the individual, and as a way of ensuring justice (in the sense that individual rights are safeguarded). A further description of this importance, also of the wider field of research ethics, is found in Chapter 3 in the resubmitted D91.3.

This chapter reiterates the most important information with regards to guidelines for privacy and data protection that has been given to the consortium before and after the submission of the first Ethical Monitoring Report (D95.31). The information is given to underline what the relevant guidelines and recommendations for ensuring "best practise" [6] with regards to research ethics (still) are in DRIVER. In addition, as stated above, since the submission of the first Ethical Monitoring Report, new DRIVER partners have undertaken research activities that require, or might require, various kinds of approvals, hence this part of the report aims at giving a state-of-the-art with the most updated and relevant guidelines concerning the protection of privacy through data protection measures.

In response to the comment from the Year 1 review, stating that the first Ethical Monitoring Report was a at times "a bit idealistic", PRIO would also like to highlight with this report that DRIVER aims at upholding and enforcing best practice when it comes to research ethics, and in order for this aim to be reachable, an element of idealism could be seen as a necessary prerequisite for aiming to implement such standards. However, this report, and the overall continuous effort to monitor the process of obtaining data ethics approvals by the DRIVER partners, also aims at providing realistic, hands-on guidelines that are useful for the partners (e.g. in D91.3 and D95.21). As the descriptions from the questionnaires indicate (see chapter 4), PRIO has reason to believe that this effort has been carried out in a satisfactory manner.

2.1 Special Clause 15

As stated in the previous deliverables D95.21 and D91.3, in the workshop held by PRIO during the General Assembly at the DRIVER week in Ispra in February 2015, and in multiple bilateral communications with consortium partners, many research activities are and will be subject to approvals or notifications as regulated by SC15, such as most of the interviews and experiments.

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 DRIVER, it is the task of WP130 to monitor (to collect and forward to the project leadership and the Project Officer) the ethics approvals that are needed for the project activities, but not to obtain or approve them on behalf of the partners. For the latter, PRIO does not have the authority to do so. Task leaders, or the data controllers (defined as the person or entity which determine the purposes and the means of the processing of personal data), as indicated in the DRIVER DoW, are ultimately responsible and accountable for obtaining the appropriate approvals (or submitting the appropriate notifications if the relevant DPA only require that), on the basis of information given in both the D91.3 and D95.21, as well as on other occasions.

A list of contact information to the different national data protection authorities within the European Union is available at:

http://ec.europa.eu/justice/data-protection/bodies/authorities/eu/index_en.htm

In order to avoid what can be called “ethics dumping” (see chapter 5.3), when in doubt of where an application or notification should be submitted or obtained from, the partners are generally encouraged to adhere to the jurisdiction with the highest and strictest standards (e.g. in cases where data collection transcends national borders).

2.2 Interactions with EU Data Protection Authorities

The first question in the Ethical Monitoring Questionnaire had to do with basic principles for ethical research, i.e. if the respondent or his/ her institution has been in contact with local ethics committees or Data Protection Authorities.

The great majority of the respondents report to having been in contact with local ethics committees or Data Protection Authorities. The great majority also report that they have not encountered any problems or challenges in doing so for the reporting period. The general feedback is that the most Data Protection Authorities only require notification of the activities, and does not formally need to approve them. For several partners, approval is only needed when sensitive data [6] is collected, otherwise notifying the Data Protection Authorities (or similar) is sufficient. Some respondents even indicate that they are under the impression that the authorities do not want to be "bothered with such topics", and that they "do not feel obliged to take a lot of time and any responsibility for checking the research design". Others have been briefly in contact with Data Protection Authorities simply to confirm that the activities abide by the relevant law. In several other cases it has become clear that neither approval nor notification is needed for the activities that were initially expected to need it. This can e.g. be explained by the fact that there have been changes in the content of the relevant activity, since the table where these activities were originally prepared by ex-SP9. Other respondents report that there were some challenges with the responsibilities and regulations with regards to cross-border activities, but that these issues have already been sorted out.

A handful of respondents report that they have not been in contact with the Data Protection Authorities, but none of the same respondents report, when asked, that they foresee any particular challenges or problems with obtaining the appropriate approvals (if they are at all needed). This can for example be explained by the fact that the relevant national guidelines have been adopted and followed for the activity at stake, and that no further interaction was necessary. Furthermore, most of them report that they do not actually need it.

2.1 When is Approval Needed?

Deciding whether or not approval is needed, is the first step in fulfilling the requirements for good research ethics. To assist the partners in making this decision, the following paragraphs are more or less reiterated from the first Ethical Monitoring Report (D95.31), as it contains basic information that is still relevant:

The first and basic question is whether personal or sensitive information is going to be collected at all in the activity. If that is that case, in practice, to find out who controls the contents and use of the personal information kept, an organisation should ask itself the following questions:

- Who decides what personal information is going to be kept?
- Who decides the use and purpose to which the information will be put?
- Who decides on the means of processing of personal data? [3]

If the organisation controls, and is responsible for the personal data that it holds, then it is legally responsible for the data, and is defined as the *data controller*. If the organisations holds and processes, but does not have responsibility or control over the personal data, it is defined as the *data processor*. It is the data controller that should seek approval or submit a notification, if needed. As previously stated in for example D91.3 and D95.31, personal data can refer to practically all forms of information that a researcher might hold. Personal data is information relating 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 [6]. 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, and a person's identity can be obtained in different ways:

- Directly from identifiers such as names, addresses, postcode information, telephone numbers or pictures[8] [4],
- Indirectly from (cross) identifiers which, when linked with other publicly available information sources, e.g. information about workplace, occupation or characteristics like salary or age [4].
- 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.

The table[9] below indicates whether data protection approval [6] is likely to be needed for the activity in question. The information has previously been given to the consortium in D91.3, D95.21 and D95.31.

Is personal data being collected?		
WHAT DO YOU DO?	**IF YES**	**IF NO**
Do you collect directly identifiable personal data[10]?	Data Protection Approval needed.	Data Protection Approval might be needed (see next

[8] Note that images are also regarded as personal data if the person may be identified.
[9] The table is based on information from the Norwegian Social Science Data Services (NSD). See https://trygg.nsd.uib.no/personvern/meldeplikt/meldeplikttest

		question).
Do you collect indirectly identifying personal data (such as background material that might identify individuals)[11]?	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 indirectly identifying personal data.

Table 1 Is personal data being collected?

The next question in the questionnaire asked if the respondent had used, or planned to use the template for ethics approval prepared by PRIO. While nearly half of the respondents report that they have used, or will use, the "Application for Research Ethics Approval" provided by ex-SP9 in D91.3, a few more report that they did not, or do not plan to, use the template. In the comments, this is explained by several reasons. For example that the activity turned out to not be needing approval, that the respondent is not the responsible for that in the organization (hence cannot decide whether to use it or not), or that a similar request/ form was developed in exchange with ex-SP9 due to the fact that the template was not ready for the relevant partner at the relevant point in time. For five of the respondents, the template is planned to be used at a later stage, and only one respondent reports that he/she did not know that the template exists. The latter could potentially be explained by the circulation of the individuals that have been involved in DRIVER in the past year, and as this can maybe be considered to be a more general administrative challenge, it will be investigated by WP130 how in particular the resubmitted D91.3 (Ethical Procedures, Risks and Safeguards", which

[10] Such as name or national identity number. 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".

[11] 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.

contains all the relevant guidelines and checklists for research ethics in DRIVER, can be circulated again to the full consortium in a constructive manner.

2.2 Potential New Challenges in DRIVER

In the questionnaire, PRIO also asked whether the partners have experienced any ethics issues in DRIVER that they have not experienced previously. The great majority of respondents report that they have not experienced any ethics issues in this second reporting period that they have not experienced before. However, there are some additional comments given on this topic. First, it is raised that the disclaimer that is to be used for the volunteers [6] in one of the experiments is far too extensive, and the respondent expresses concerns that this may discourage people from participating. This issue, which was called a "formalization of research ethics", was taken up with the Ethical and Societal Advisory Board at the second meeting (minutes available in D95.12). While PRIO acknowledge that the practical routines can seem unnecessarily extensive for some partners, there is also a need to remind the consortium of three important issues in this regard.

1) These are not rules and obligations that PRIO have developed, but formal requirements for research projects funded by the EU and ethical obligations for research involving human beings (e.g. due to respect for the participants in the research). I. And 2) that the rules and regulations are in place to protect both the researcher, the participants in the research, and the integrity of the results of the research, and 3) that PRIO cannot force anyone to follow these rules and that PRIO cannot formally approve any approach by a partner, but that PRIO gives guidance on how to ensure following best practice when it comes to ethics concerns (for a closer discussion of this, see Chapter 3.4.1). A potential ultimate consequence of failing to uphold basic requirements for research ethics is the issuing by the Commission of an Ethics Audit. Such an audit can theoretically result in an amendment of the grant agreement. In severe cases, it can lead, upon the decision of the Commission services to a reduction of the grant, its termination or any other appropriate measures, in accordance with the provisions of the grant agreement [5]. Furthermore, some partners report that they have not really had to deal with ethics issues before, and again, this points to the challenge that was also described in the first Ethical Monitoring Report; that the gap between the experienced researchers in the project and those partners who have never dealt with research ethics before, makes giving the appropriate (and detailed amount of) information a balancing-act.

Another partner point to the large number of unaffiliated volunteers [6] that will eventually take part in the experiments, and report that:

> (…) the DRIVER experiments will eventually involve citizens with no affiliation to the project. The number of such participants in some experiments could be huge, and it is impossible to get a written "informed consent" in advance. For this reason we decided to have an online form that volunteers need to click-through in order to participate in the exercise. Only, if everything has been accepted, the volunteer receives the experiment code, which can be used to download the CrowdTasker application.

While this “click through”- solution is suboptimal, because it makes it possible to just precisely, click through them without reading, the solution is understandable due to the large number of volunteers [6] involved. For the Joint Experiments, PRIO will follow up with the partner at stake, and see whether complementing solutions might be possible, to make it more difficult to “click through” the questionnaire. For example, one could include a question to check the consistency of the answers given in previous questions. One partner reports that their research including people with disabilities is a new experience, but that this was addressed by adapting research guidelines given by their National Disability Authority. Another partner reports that while they have not encountered new challenges yet, they are mindful that there are risks, referring to the DRIVER website being hit by a spam-mail that contained offensive imagery/ language. However, relating mainly to IT-security, this is not considered to be a topic for WP130.

2.3 Research Ethics Procedures in DRIVER

As already stated in the first Ethical Monitoring Report (D95.31), the DRIVER experiments are not taking place in a legal vacuum, but in a wider context of e.g. changing legislative frameworks and the emergence of new ways and possibilities for planning and conducting research. Methodological innovation is a *sine qua non* for the study of a changing society and its ever-changing constituent individuals and institutions, and following, new (research) methods pose new ethical problems [8]. So far, the DRIVER experiments and activities have not posed any major ethical problems that could not be solved by taking into account the guiding documents that had already been prepared by PRIO in previous deliverables. Of course, this does not mean that no such challenges might occur in the future phases of the project (beyond M24), in which case they will be addressed in following reports.

All, but two, of the respondents reports that they are not missing any information with regards to research ethics (such as templates or guidelines on particular issues). Some of the comments in this section include specific issues like the wish for a template that could be used to collect approval from external volunteers [6] to disseminate video materials/ pictures of activities they are included in. Other issues relate to the more general approach to research ethics on the EU- level, i.e. that a clear and low-effort process should be guaranteed by the EU, and that an extra effort should be provided by the EU to each partner that has to take care of this process. While this is not an issue that PRIO/ WP130 can deal with within the scope of DRIVER, it is the impression of PRIO as WP130 leader that a lot of the perceived gaps in this effort can be closed simply by providing the information about the efforts that have already been undertaken by PRIO to the partners in a broader manner. In other words, several templates and checklists already exist (and have been used by the majority of the respondents to these reports), but an extra effort seems to be needed to distribute the information again. However, during the reworking and resubmission of these deliverables, it did not seem sensible to distribute them again to the consortium; hence this has been a pending issue in this phase. However, PRIO has all the while been available for questions and discussions with regards to particular issues, and has given advice in specific cases on several occasions.

Other feedback include that more information would be useful (stating that ethics is a broad-based concept and that some examples of where ethical considerations play a role and/or a targeted "ethical do's and don'ts" list for the various DRIVER stakeholders could be very helpful). While such checklists have not been developed per stakeholder in DRIVER, the resubmitted version of D91.3 includes a list of general recommendations for ethical research, as well as a list of general recommendations for the DRIVER experiments. Again, the task from a WP130- perspective is here to ensure the distribution of these lists. D91.3 also includes a suggested template for informed consent, and a general template that could be adapted and used for research ethics approval (both in the original and in the resubmitted version).

3 Human Participants in DRIVER Activities

3.1 Inclusion of Vulnerable Groups

A group is often referred to as vulnerable, when there is special reason to believe that the individuals in the group could have particular problems with giving their free, active, informed consent to research being conducted with or on them. When it comes to the inclusion of human participants in DRIVER, in particular relating to the inclusion of vulnerable groups (e.g. disabled, elderly, minors), almost every respondent reports that their research in DRIVER does not include such groups. Specifically, a few comments are shared, which illustrates how this was taken care of in the relevant cases, where the research included 1) elderly and 2) people with disabilities. For the research including people with disabilities:

> "We consulted in advance with National Disability Authority on research design. Researchers had personal experience of people with disability. All participants asked in advance if they would like any assistive technology to be provided or other communication assistance such as a sign language interpreter. Independent Disability Support Office acted as host".

And specifically, for the research including the elderly:

> [the] "researcher leading group had experience in dealing with elderly. Steps taken to ensure communications explained and opportunities for clarification offered. Organisation led by and for the elderly acted as host and cleared research approach in advance".

Others report that they have conducted workshops for elderly about crisis communication, and considerations like choosing a location for the workshop that was well known for the participants and easy accessible, was made. The same partner also made sure to conduct the workshop in the local language. Finally, another respondent confirmed that discussing ways of including and adapting the [research] environment to vulnerable groups has been a central part of all the experiments. And furthermore, that this discussion in itself helped them ensure that the wellbeing of these participants was monitored. In addition, the partner reports to having worked with their other partners in making sure that the facilities they worked in were accessible to all participants and that different needs were provided for. Finally, as part of the experiments, the facilitators were trained on how to adapt the space and activities to different needs and this has been a priority throughout the trainings. One partner report that they collect information about the "health status" of the volunteers [6] to make sure that they are in a healthy condition. To some extent dependent upon the definition of the actual question, "health status" is to be considered sensitive information, and PRIO will remind the relevant partner of the need for ensuring that the appropriate approvals are in place for this activity.

3.2 Affecting the Public

When it comes to the question of whether the research activities in DRIVER have had or could have an effect on the public (such as bystanders or people in the close proximity of the experimentation sites), all but one of the respondents reports that this has not been an issue. For the most part, the experiments are taking place in closed environments with crisis management professionals and volunteers [6] that have been made adequately aware of the experimentation context, and do not represent any ethics issues. However, some comments are given under this point, and these are incorporated in the following text.

One partner reports that "while at first, the groups for testing our tools were small and the experiments confined to well-defined tasks within specified scenarios, we increased the number of volunteers and the complexity of the tasks continuously during the experiment rounds. For the final demonstration, we envisage to involve even bystanders, if they are interested in participating as spontaneous volunteers". The same partner report that for some of the more large-scale experiments it can happen that there will be bystanders who are not informed about the activity (and that will choose to participate). If the later happens, the partner report that these bystanders *de facto* become volunteers who then have to read the informed consent before downloading the application used in the experiment and finally participating.

The design of the Joint Experiment 2 is just getting started, and this experiment will include more elements from Subproject 3 (in other words, more volunteers and participants), making this a point that needs to be followed up by WP130 to ensure that no major ethics issues arise in the design and implementation.

One issue that was also raised in the first Ethical Monitoring Report, namely the issue of UAV's collecting aerial images of cities (that could also include people), was mentioned again in this reporting period. While it is clear how this is handled in e.g. Germany (with regards to requirements for picture resolution so that specific individuals cannot be identified from the images), it is not clear- at least not for the particular respondent- how this is handled in other countries such as France and The Netherlands, where the use of UAV's (RPAS) will be needed, e.g. for the Final Demo of DRIVER. This is also an issue that needs follow-up, but most likely via tasks dealing with legal issues in WP130.

The issue, or a similar issue, was raised with the ESAB already.

The question was then: If data collection, e.g. per drone, happens across different countries and data is stored in yet another country, who applies for approval? The answer was that generally the task leader from the country where data is stored and used is likely to be responsible. In doubt, the Data Protection Authority with the highest standards should be applied to. Given that this standard has been met, all other countries are likely to agree (best practice). In addition, UAV's/ drones will need aviation approval for all countries, but that is not PRIO's responsibility. Furthermore, before any application is issued, 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.

3.3 Are Human Participants at Risk?

None of the respondents report that the individuals participating in the research activity or experiment are at risk of being harmed, either physically (unsafe working environments etc.) or psychologically (disproportionate stress, discomfort etc.). However, some comments are given to nuance these answers, and these are reflected in the following. The majority of the comments (given that all respondents answered "no" to whether participants were at risk of harm) are clarifications or explanations of why this was not an issue. For the most part, the activities include playing a situation that is well- rehearsed and familiar to the participants. Several of the respondents report that they have informed the participants that their work will not be evaluated (especially important when the participants were employed in their day-to-day-roles). While some report of potential risks of stress for the participants, in the sense of reasonable stress from being observed during the activities, or that in some experiments, practical activities will be performed, these are not considered major issues that need further follow-up. While these physical activities might entail a limited risk of injury, these are not specifically dangerous activities, but rather activities such as filling sand bags or physical interaction in a team (team building exercises like balancing a wooden lath). The activities mentioned are not considered to pose any disproportionate risk or stress to the participants, and one respondent sums up this position by stating that travelling to the experiments is most likely more risky than the experiment themselves. One partner report that in cases where volunteers are involved in field trails that require physical activities, a DRIVER expert with expertise in managing volunteers will be present.

It is also clear that some precautions have been taken to ensure the well-being of the participants, something the quotes below demonstrate:

> "Creating a safe environment is one the priorities of the experiments we have conducted. One of the experiments required participants to carry out some forms of moderate physical activity. Accordingly, safety has been an aspect we have monitored and up-to-now we have not encountered any indications of physical or psychological harm."

The experience and professionality of the organizations responsible for the volunteers is also highlighted:

> "Experienced volunteer managers from professional responder organisation will take care for the safety of volunteers. The issue is addressed in experiment preparation and code of conduct."

One of the answers had to do with how the use of social media platforms under some circumstances may have harmful psychological repercussions on some users (mainly the case for individuals using platforms such as Facebook or Twitter). Although research indicate that the use of such media platforms may indeed have harmful consequences for some particular groups of users[12], it is clear that the DRIVER Community Platform (DCP), is intended only for professionals in the crisis management field, and thus is not intended for interactions with regards to their personal life. Specifically, the Terms of Services of the DCP also includes a specific paragraph "Expected behavior of members", informing all the members to "Refrain from using foul or offensive language" and "Treat all other ARTTIC Community Management Platform members in a respectful and courteous manner at all times, even in the event of disagreements" in order to prevent this kind of situation. While some sort of misuse of the online platform could potentially happen, this would become a management- related issue for the organizations responsible for managing and running the platform, and not an ethics issue for WP130 to safeguard any further against.

3.4 The Importance of Informed Consent

The concept of 'informed consent' is at the core of an approach that respects the right to privacy. Informed consent implies that the individual whose data is collected is informed about the purpose of the research, and consents to the use of their data for these purposes. The need for, and importance of, using informed consent sheets whenever individuals are involved in the research activity was already highlighted in the first Ethical Monitoring Report (as well as in D91.3). PRIO provided a template that can be (adapted and) used for obtaining informed consent from participants in D91.3, and this has later been circulated with other deliverables as well. Every respondent, apart from three, report that they have used or plans to use, the informed consent template provided by PRIO in D91.3. One quote illustrate how the template have been adjusted to an online format, and applied to a large group of volunteers: "In February 2016 our field trail attracted 200 volunteers from Austria and Germany, who had to read and sign an online informed consent prior to participating in the exercise. The material developed for this purpose was produced on the basis of the template provided by SP9". For platform owners, the decision to use the form or not is up to the partners that do experiments on their platform, and its use can thus no be guaranteed, but for the rest of the comments given in response to this question, the template has seemingly been well received and used. One of the respondents explained how the informed consent sheets were distributed to the participants at least 24 hours in advance of the activity, and that a printed copy was also provided on-site. Furthermore, that the participants were given the opportunity to ask for clarifications, and those participants with visual impairment and poor literacy skills had the form read to them in advance by a person of their choice. One respondent reports that a translation of the template to the local language was necessary. Furthermore, when it comes to informed consent, and the potential problems relating to it, almost all of the respondents reported that they have not (or does not foresee) any particular challenges. However, there is one issue relating to the length of the

[12] See for example: http://www.theguardian.com/society/2015/sep/11/teens-social-media-night-risk-harm-mental-health-research

informed consent form, in a case where it has to fit within the interface of a mobile application. The challenge here, as reported by the relevant partner, is that "If we put a long text on a smartphone, nobody will read it. If we provide only a short version, we risk missing something important". This issue will be followed up with the DRIVER Ethical and Societal Advisory Board to ensure that the "best practise" [6] is followed, but in the second meeting with the ESAB, the general advise to DRIVER was the following: "Collecting informed consent via a form in an application on a mobile phone is unsatisfactory in terms of how much information can be included in the form's text. People always tick boxes on phones fast and without reading the full terms and conditions".

3.4.1 "Formalization of research ethics" expressed by informed consent procedures

Another issue is mentioned by two respondents, which was also raised in the questionnaires from the first Ethical Monitoring Report. These two comments are interpreted by PRIO to cover the issue that was referred to in Chapter 5.2.3 of the first Ethical Monitoring Report (D95.31) as a "formalization of research ethics", that was perceived to have unfortunate effects on the success of the activities. It is described by two respondents in the following way:

> "Actually, if participants offer their time, it is not preferable to bother them with additional documents for them to read, and ask for their approval beforehand. But no major problems were encountered".

> "It puts additional effort and stress on the participant to be confronted with the informed consent sheet and information (besides understanding the project, the experiment, their role, the solution etc.). This may annoy or even exclude potential candidates".

The issue of informed consent as described above, relates perhaps in particular to the inclusion of external (to DRIVER) individuals in the projects activities, where volunteers are likely to aspire to partake in the subject of the matter and not engage with the more formalized rules of ethics. In other words, when volunteers, that are not affiliated with the project (i.e. not attached to a recognised voluntary agency that have trained them for disaster response and has a mechanism to put in place to address their use in an emergency) [6], are recruited to partake in an activity, there is a risk that the formalisation of ethics (i.e. via extensive informed consent forms) may effectively discourage them from participating. To follow internationally recognized standard procedures for research ethics in a project like DRIVER (or any other research project for that matter) is unavoidable, and it is a fundamental condition for scientific soundness and good practice in research (and again: is not a product or invention of WP130). DRIVER involves the collection, processing and storage of data derived from individuals, both those internal and external to the project. At the very core of ethical research are rules and guidelines for the participation of human subjects in 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 ethical questions and issues within DRIVER. From the perspective of WP130, the

ambitions for ethical and societal considerations and impacts that SP9 previously and after the restructuring, WP130 is tasked with and is pursuing within DRIVER, should (still) be seen as an added value of the project.

One final remark can be made in this regard. While "bothering" or "annoying" participants with paperwork such as informed consent sheets before they can participate in a certain activity can be seen as unnecessary for some partners in some contexts, the ultimate aim of WP130 is till to maintain the highest level possible when it comes to research ethics in DRIVER, and in order for this to be possible, the routines described in D91.3 (which are based on fundamental principles for best practise for research ethics for EU- projects) [6], must be followed. Finally, PRIO remains available for discussing alternative solutions to particular challenging cases, and it should be pointed out that the template that has been developed by PRIO is flexible, and can be tailored to different occasions, depending on what the most prominent issues are.

This issue of a "formalisation of ethics" was also raised to the ESAB in the second meeting, since it was mentioned also in the questionnaire from the first reporting period. The Board was invited to give general comments and input on this issue. The ESAB suggested stressing the consequences of not having the appropriate procedures in place, in case something occurs. Although it might seem very unlikely that something will happen, it is still a possibility that e.g. collected data might be misused or that participants may feel uneasy by not being informed properly of the activities. Generally, the partners will have to understand that ethics is not a matter for "watchdogs", but for the legitimacy of the project, for building trust and for best practice. Generally speaking, none of the members of the ESAB present at the second meeting have experienced participants saying no to participation in research after they have been informed. Rather, the more information is given, the better and reassured participants are. Board member Petousi later commented further on this issue via email, stating that while there is no way around the formal agreement by participants, one lesson learned in the formulation of such requirements is to place less emphasis on the contractual and legal requirements and more on the building of trust and best practice. Legal and contractual obligations at least for some partners can be equated to "bureaucratic" requirements which can be fulfilled by ticking boxes, filling papers and providing permits and approvals. This is not a concern only for DRIVER (to quote Petousi: "On the contrary I believe that this is a project with genuine concern about ethics"), but the state of affairs with regards to ethics in research.

3.4.2 The Quality of the Informed Consent

As described, informed consent continues to be very important in the project. A key component of full, active and real informed consent has to do with the amount of information that is provided to the individual signing the informed consent sheet. The answers to the question about the completeness of the information provided in advance to the participants are reflected in the following. For the large majority of the respondents, they are able to provide complete information about the activities in advance, without any conditions. For the remaining group, they report that

they are able to give some information, but not all the information. In every one of these cases, the reason for this is reported to be the fact that some information regarding the content of the crisis management scenario that the participants are to be exposed to during the experiment/ experimentation activity needs to be kept from the participants beforehand, in order for the activity to be realistic and useful. Particularly, when the participants are to solve a concrete problem via these activities, it is absolutely clear that the information about these problems and the detailed steps of e.g. the simulation procedures cannot be given in advance. In fact, this is part of the very core of the experiments, which are defined as: “A scientific procedure undertaken to 1) make a discovery, 2) test a hypothesis, or 3) demonstrate a known fact. Experimentation in DRIVER involves the testing of novel “solutions” (a mix of existing and new technological, conceptual or organizational solutions) under controlled conditions, to assess their effectiveness and possible impact. The term experiment is used for all types of experimentation activities in DRIVER” [6]. However, none of the cases where information is being partly withheld is considered to be of such a nature that this poses an ethics issue for the project. As long as the context and the types of activities that the participants are to be involved in can be revealed in advance, this should not be an issue. For examples, a group of volunteers will be given the information that the simulation will include some light physical activity, but not that this really means e.g. to fill sand bags during the experiment.

4 The Role of WP130 in DRIVER

For the final part of the questionnaire, the interaction between WP130 (ex- SP9) was the main focus. From the research ethics perspective, the content of the new work package WP130, "Research Ethics, Scientific support, IPR & legal issues" consists of the activities from WP95 & T91.3 in the original DRIVER structure. While there have been some practical and structural changes, the content of the tasks relating to research ethics (as led by PRIO) remain the same under the novel structure of the project.

4.1 Easing the Implementation of Ethics

One question in the questionnaire asked how PRIO, as WP130 leader, can make it easier for [the relevant partner] to deal with their ethics issues of the research. For example, is any information missing, such as templates? Is information provided in the right format? The comments to this question are reflected in the following. The large majority does not have any suggestions or complaints about the procedure pursued by PRIO so far. One partner report that PRIO has provided very detailed information on how to proceed to get approvals from data protection authorities and templates for informed consent to be signed by experts and other non-partners' participants in the experiments or interviews to be conducted within the project. Some underline that there is no need "so far" (indicating that this questions should be part of the third Ethical Monitoring Report as well), one respondent specify that the support to date has been "excellent and sufficient", while another mentions that while the support has been fine, but that "the EU and REA should make it more easy". The latter statement should be seen in relation to the "formalization of ethics", as discussed above. In terms of EU making it easier, PRIO will follow the development with regards to the Data Protection reform in the EU, to investigate whether this will have consequences for DRIVER, i.e. the suggested establishment of one common Data Protection Authority for Europe, could have the potential to ease implementation of ethics in research.

A few respondents reported that there were certain kinds of support or information that were missing with regards to research ethics. This has for example to do with the wish for a WP130 Point of Contact for the Joint Experiment 2, who knows what is planned, and can advise the experiment leader on the difficulties the experiment leader might face and help in planning ethical actions in consequence. The respondent, who raised the issue of the collection of aerial images via UAV's in Germany and The Netherlands, raises the issue again under this question. The need for a potential contact point for Data Protection Authorities in The Netherlands is mentioned, as well as a general clarification with regards to the potential different requirements in these two countries. For example, it is clear that in Germany, an explanation that the picture resolution will be less than 20 cm and people can only be detected but not identified is sufficient to comply with data protection regulations and now official approval is necessary, but it is not clear how this in handled in The Netherlands. This needs to be followed up both for Joint Experiment 1 and the Final Demo (also for

France). Another comment suggests that “there might be some added value to consider the relationship with WP130 with legal, sustainability, and exploitation issues”. One partner reported that: “It would be helpful to have a guideline on how to deal with volunteers in experiments and to know more about insurance related topics in case someone is getting hurt during the exercises”. Finally, one respondent mention that “it would be really helpful that the information about considerations to be taken into account for an experiment could be provided in the form of a checklist”. In the latter case, this actually does exist, and needs to be forwarded and distributed again. Similarly, another partner requested clear guidelines, e.g. a decision tree, on how to find out if a specific experiment requires ethical approval. A step-by-step instruction on this matter was included in Chapter 5.2 of the resubmitted D91.3, and a table summarizing the main points was included in the first Ethical Monitoring report (as well as the current report), but this request demonstrates that PRIO have to ensure that this information once again reaches the full consortium. Furthermore, the same partner also reports that it would be useful to have a table with the different authorities responsible for dealing with ethics and data protection in each country. PRIO will not make this table, but a link to a list of contact information to the different national data protection authorities within the European Union was provided in the first Ethical Monitoring Report, and in the current report. The relevant partner will be reminded of this list.

5 The Ethical and Societal Advisory Board (ESAB) – Report from the Second Meeting

The Ethical and Societal Advisory Board (ESAB) is an independent committee that advises DRIVER, and in particular WP130 (originally WP95 in SP9), about ethical challenges and societal aspects of crisis management and research done throughout the project. While the first meeting of the ESAB in December 2014 focused mainly on research ethics as part of what was then SP9, the second meeting strengthened the Board's focus on the societal impact- side of what was then SP9. Nonetheless, ethics issues were also discussed. The full minutes for the meeting can be found in D95.12, but an abstract is presented in the following chapter.

5.1 Content of the Meeting

The second meeting of the ESAB was held on 21st September 2015 at the premises of PRIO in Oslo. The meeting's purpose was to introduce the concept of Societal Impact Assessments (SIA) [6] to the Board, but also to give an update on the general status of the project, in terms of the effort and task in terms of research ethics. Feedback on particular questions relating to ethics issues from year 1 of DRIVER was solicited (i.e. from the first Ethical Monitoring Report & the general ethics monitoring process). After the Board had been given an update on the current and planned activities for (then) SP9, they were updated by PRIO on the particular activities with regards to research ethics. Stine Bergersen (PRIO) gave a presentation of the activities on research ethics from the first year. Since the first Ethical Monitoring Report was submitted in April 2015, and the Board met in September 2015, this information was considered to be relevant for this second Ethical Monitoring Report. The different activities that SP9 (and later WP130) carried out with regards to monitoring the status of research ethics in DRIVER were presented. Amongst other things, this presentation included e.g. the delivery of the ESAB minutes from December 2014, and the Project Officer's feedback from the first ESAB meeting, and the actions SP9 (and later WP130) took to answer to this feedback.

The preliminary feedback from the Year 1 review meeting included the following issues which were presented to the Board:

- The ESAB is highly valued as an independent committee.
- It is challenging that not all the partners are at the same level of understanding when it comes to research ethics (various experience and familiarity with research ethics).
- Approval is needed before the start of the research activity, or at least as soon as the partners (the task leader) know the design of the activity.
- Collected "packages" of approvals should continue being forwarded to the Commission.

- In general, there is a need for clear and practical procedures, which stress that it is the task leaders' responsibility to obtain the correct and relevant approval

5.2 Actions Taken by PRIO in the Reporting Period

In response to this, PRIO undertook the following actions in the second reporting period, which was presented to the Board:

- A workshop on research ethics was held by the SP9 leader during the General Assembly at the DRIVER meeting week in Ispra in February 2015.
- A letter was drafted by PRIO and sent by the Project Coordinator to the full consortium to "sharpen the tone", to reiterate the procedures for ethical approvals, and once more clarify the different responsibilities. The letter also contained references to all relevant deliverables, as well as all the relevant templates for data protection approvals and informed consent.
- In addition, throughout the year, bilateral follow-up and discussions have been carried out with the partners needing it. Several reminders of deadlines have also been given, both collectively and individually.
- PRIO has also collected and forwarded all approvals for the current period, which was submitted to the REA and the Project Leadership October 2015.

Regarding the latter point, the presentation to the Board by PRIO also highlighted that overall; some partners are concerned with demonstrating best practice, while others still need to be individually reminded about the necessity for approvals. The process as a whole requires a lot of dialogue and flexibility, mainly because many of the activities by the partners are still under planning, making it difficult to determine if and what kind of approvals might be necessary. In addition, many of the partners are either not used to dealing with rigid research ethics guidelines, or not used to dealing with it for the kind of activities carried out within DRIVER, i.e. they might do it in their day-to-day activities, but not as a part of a research project with all those scientific requirements that entails. In sum, research ethics still needs quite a bit of follow-up, which the team at PRIO, together with the coordinator are trying their best to accommodate for.

The first Ethical Monitoring Report questionnaire also asked what (ex-) SP9 could do better in terms of research ethics. Some suggestions were made (PRIO's answers below the suggestions):

- Design a checklist for experiments to identify whether one needs approval
    - PRIO: PRIO has been contributing to a section in the Experiment Design Manual in WP23, making research ethics mandatory for everyone dealing with experiments. PRIO will also contribute with more refined versions in the follow up deliverables in WP23, and contact with SP2 has been continued. In addition, the first Ethical Monitoring Report reiterated the guidelines and the templated necessary for

fulfilling the ethical requirements. In addition, a checklist for research ethics for experiments was submitted as part of the resubmission of D91.3.

- Less theoretical information and less “concepts”, and more recommendations in “action form”.
    - PRIO: This is a challenge, and difficult to tailor to the different needs and levels of experience of the 37 DRIVER partners, but (ex-) SP9 has, since the first deliverable submitted in M6 of the project, aimed at providing guidelines and routines in understandable and applicable form. The ESAB as well as PRIO understand that partners will have to be sensitized long-term. A use of small scenarios and examples to explain difficult situations is recommended, e.g. why anonymization is important or why participants need to be informed. Such examples were integrated in the resubmission of D91.3.

- Establish a contact point in each country to deal with local authorities.
    - PRIO: This is simply not possible, due to restricted resources. It is impossible for SP9/ WP130 to interpret the legislations in all the different partnering countries. However, a list with the contact information to the different European DPA’s (which are the entities actually in charge of making decisions with regards to research approvals) was provided in D95.31, and is also provided in this second Ethical Monitoring Report. Additionally, such a point of contact would undermine the general responsibility of the task leader to deal with and organize research ethics him- or herself.

- SP9 should review the design of the experiments before applications (to the DPA) are submitted.
    - PRIO: This has been followed up bilaterally in difficult cases, and PRIO have been, and continues to be, available for questions. Reviewing every approval is, however, not a standard a) because of restricted resources and b) because approval applications are often written in the respective country’s language.

5.3 Discussions with the Board

One question to the Board derived from the first Ethical Monitoring Report during the second meeting was how the ethical component of (ex-) SP9 could be further strengthened, and how to keep fostering the awareness of research ethics with the least amount of stress and extra work for all partners, as well as for (ex-) SP9. Since the Board acknowledged that it is already a lot of work to oversee and uphold a minimum threshold for research ethics, i.e. a lot has already been done to inform the consortium, it was difficult to give advice about this particular point. One approach could be to observe whether there is a pattern in who gets back to PRIO first and then target those who are slower in their response specifically. Expectably for companies that are not used to deal with academic work, but rather operational crisis management, the procedures will certainly be less

familiar. However, no such pattern could be observed just yet, but should it emerge in the future (beyond M24), PRIO will follow this advice.

Furthermore, the Board mentioned the following points about the larger topic of approvals from Data Protection Authorities:

- PRIO will, over the years that DRIVER runs, get an overview of data protection approval procedures in the different countries. Such an overview does not exist as of now. Through that, the collected forms and documents about the procedures could potentially be of value beyond the project's scope. PRIO answered that this is true, but procedures and forms are currently for the most part held in the respective country's language. At the moment, no specific effort is available to create such a generic "overview of approval procedures", but PRIO will keep this suggestion in mind for the future, meaning beyond M24 (as the requirements from the partners could potentially slow down over the years).
- There is a new European Directive concerning Data Protection coming. PRIO will pay attention to this and check whether it impacts DRIVER's work.
- The Board pointed to the potential danger of so-called "ethics dumping". Meaning that should there be different standards in research ethics across Europe, application procedures are often "dumped" on the partner with least difficult procedure. PRIO replied that by following the approval procedures as per task (through the task leader) – as done in DRIVER - avoids such a problem, unless this was already taken into account in the planning of the project, which cannot be expected. Should PRIO face the case where it is unclear who should be applying for approval, it will follow the Board's advice to encourage those partners with expectably the highest national standards to apply in their country. Through that, a best practice in research ethics can be guaranteed.
- It cannot always be expected that Data Protection Authorities make a full review about an application, or gives an "approval" as such. For many authorities it suffices to apply or to submit a notification. PRIO shares this experience, and in such cases will continue to forward the submitted application or the reply of the respective authority.

5.4 Presentation of the first Ethical Monitoring Report

During the meeting, PRIO presented the board with a summary the first Ethical Monitoring Report (D95.31) which was submitted in M12, and eventually approved. The first Ethical Monitoring Report was submitted in April 2015, and it included the feedback from over 25 DRIVER partners. The report addresses key ethical issues from Year 1 of DRIVER, and the most challenging ethical issues as seen by the partners and by SP9. The presentation of the report included a description of the sources of information in the report (mainly a questionnaire filled out by all the partners), and some key findings mentioned in the report (for details, see the PowerPoint presentation in annex to D95.12). It was stressed that the questionnaire distributed to the partners in order to solicit input was also an awareness-raising exercise, since it was clear that not all of the partners indicated in the DRIVER

DoW had actually started the activities that need ethical approvals. Therefore, the questionnaire also asked some more general questions that might be useful for the partners to reflect upon during coming planning of e.g. experiments. It was also stressed that only 0.2 PMs are set aside for this task as per DoW, which is not much, given that the input from over 25 partners needed to be sensibly integrated into the report.

5.5 Informed Consent & General Advice

The following problem raised in the report was discussed: Does the informed consent form hamper a methodologically intended moment of surprise in the DRIVER exercises/ experiments?

It was presented that for some partners it was difficult to obtain informed consent in advance of the activity, since the activity should contain an element of surprise in order to be realistic (e.g. the use of different scenarios in the exercises). The Board was asked to give advice on this point.

The answer from the Board was that in general, as much information as possible should be given in advance. It is also possible to obtain consent after the activity for *special cases*. The Board also stressed that the deciding factor is the proportionality of the stress that participants are exposed to: the bigger the potential harm, the more is there a need to justify why participants cannot be informed in advance. For example, testing an alarm in a public space without informing the public in advance is not advisable. In other words, there have to be good reasons for keeping information from the participants. The participants would also need a proper debrief, and their consent is still crucial. The Board has further pointed out that in general, people will need to be informed beforehand, but they don't need to know what exactly is happening in the scenario; there still can be an element of surprise.

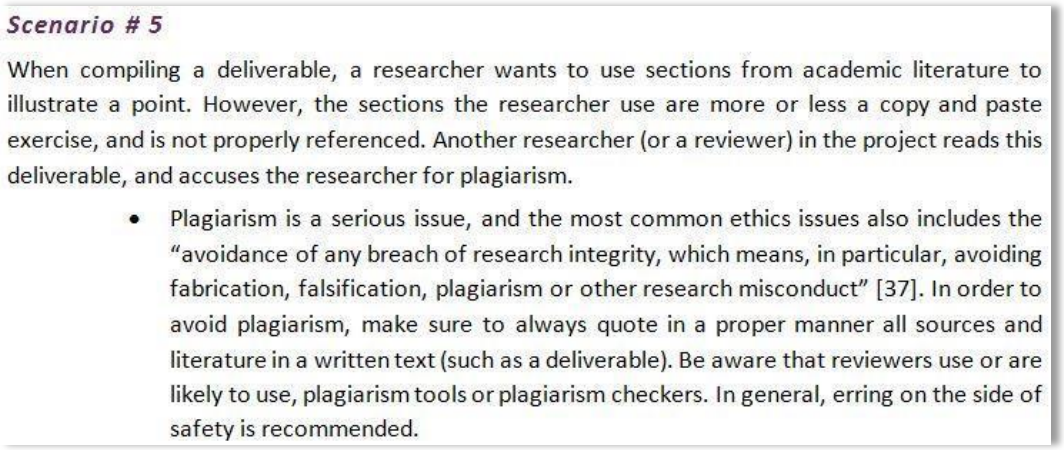
In addition, the Board gave the following advice:

- If an experiment is planned for a semi-public space, potential distress of bystanders should be minimized by putting up informative posters.
- Collecting informed consent via a form in an application on a mobile phone is generally unsatisfactory in terms of how much information can be included in the form's text. People always tick boxes on phones fast and without reading the full terms and conditions.
- Never expose people to a potentially alarming situation without getting at least a general consent.
- Provide de-briefs for participants afterwards.
- Generally, experiment scenarios should be reviewed by their planners vis-à-vis potential ethical problems. WP130 have no effort in Experimentation Design, but has been consulted in the design of the Experiment Design Manual. However, they will have to be contacted by those planning the experiments in due time. Again, the respective task leaders are responsible for ethical provisions.

5.6 Issues from the second questionnaire to bring to the ESAB

The questionnaire that informs this second Ethical Monitoring Report finally asked if there were any issues that the respondents wanted PRIO to bring up with the Board in the next ESAB meeting. The great majority did not have any suggested topics or questions, and some highlighted that more effort should be put on the Societal Impact Assessment- tasks, while the ethics issues should be reduced.

Another issue had to do with plagiarism, and whether DRIVER has a policy when it comes to plagiarism. This is relevant when there are documents that are being produced in DRIVER that heavily rely on existing research. In this case, the respondent suggests a 1-pager with ethical guidelines per DRIVER subproject and/or stakeholder group (researchers, industry, operational users, policy makers etc.). Plagiarism was one of the topics in one of the scenarios provided in the resubmission of D91.3 aimed at illustrating the complexity and different nuances in research ethics.



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" [37]. 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 tools or plagiarism checkers. In general, erring on the side of safety is recommended.

Figure 1 A scenario on plagiarism

One partner reported that "it could be useful to address the issue of an overview of the responsible authorities in each EU country", meaning an overview of relevant data protection/ ethics authorities in each of the DRIVER countries. As previously stated, such a list this has already been included in the first Ethical Monitoring Report (and in the current one). And the relevant partner will be reminded of this. Another respondent suggested the following topic: "We could do research using data (e.g. damage and needs assessment reports on past events) acquired by third parts. The reports could contain sensitive data [6] on people, villages, countries. How can we manage that?". This issue will have to be further investigated and clarified with the partner at stake, and will not be detailed further in this report. Another suggestion that needs to be further clarified and followed up it the suggestion that "It would be good to share some good practices on how to implement the ethical guidelines in different settings". PRIO will follow up on these matters with the relevant partners. Finally, one partner highlighted the difference between "private data", such as e-mail, and "sensitive private data", such as health status, and also the difference in storage, i.e. between "putting the data on a central server",(where it could be easily used for something we did not intend) and "keeping the data on the user's device" (where the user has more control over it). While the requirements for

storage should ultimately be decided by the relevant data protection/ ethics authority, this is a topic that will be discussed with the Ethical and Societal Advisory Board at the next meeting. The concern is expressed as such by the partner: “The process of ethical clearing appears to be the same for applications which just store e-mails on a central service and those that (would) store complete medical records of all users”. In reality, while the former kind of data would most likely only require a notification sent to the DPA etc., the latter would necessitate an application being approved by an ethics committee, and particular requirements regarding storage to be followed. Furthermore, the general recommendation would already be to rather impose too strict measures to the data processing than the other way around.

6 Final Remarks

This deliverable is the second Ethical Monitoring Report, documenting and addressing key ethical issues in DRIVER. The next Ethical Monitoring Report is due in M36, and will document and address ethical issues pertaining to the project in the year to come. This report has also repeated and refined some core points from previous deliverables; both to clarify some particularly important points regarding research ethics, but also to update and specify some of the previously given recommendations and guidelines. This is based on the knowledge and information accumulation that is already taking place within DRIVER, due to a more operative and practical orientation in the work, as well as new partners, constellations of partners, and the overall increased activity in the project. For the next Ethical Monitoring Reports, updates on ethical issues will be documented, and relevant issues will be discussed, but it is expected that the following reports will to a lesser degree address fundamental issues relating to research ethics, and revolve more around the practicalities of collecting the approvals, and potential special ethical challenges in the project, relating in particular to the Joint Experiments and the Final Demo.

References

[1] Marshall, G & Scott, J (eds.) (1998), *A Dictionary of Sociology*. Oxford University Press. Oxford.

[2] The National Committee for Research Ethics in Science and Technology (NENT) guidelines https://www.etikkom.no/forskningsetiske-retningslinjer/Naturvitenskap-og-teknologi/ , retrieved April 28, 2016.

[3] European Commission. Data Protection Unit of the Directorate General for Justice, Freedom and Security, *Frequently Asked Questions Relating to Transfers of Personal Data From The EU/EEA to Third Countries*. http://ec.europa.eu/justice/policies/privacy/docs/international_transfers_faq/international_transfers_faq.pdf , retrieved April 28, 2016.

[4] UK Data Archive, Create & Manage Data- Anonymisation. http://www.data-archive.ac.uk/create-manage/consent-ethics/anonymisation, retrieved April 28, 2016.

[5] European Commission, Reseach ethics. http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics, retrieved April 28, 2016.

[6] Linde- Frech, I (ed.) DRIVER Terminology (second version), 2016. Document of the DRIVER project, 2016.

[7] University of Oxford, 2012, *Data Protection and Research*. *Legal Services Briefing Note*, p.4.

[8] Social Research Association (SRA), 2003, *Ethical Guidelines.* http://the-sra.org.uk/wp-content/uploads/ethics03.pdf, retrieved April 28, 2016.

7 Annexes

7.1 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 36 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)

7.2 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."[7])
- 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.

- 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?

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

- Ethical Monitoring Questionnaire (T130.4)-

In T130.4, PRIO is tasked with preparing regular Ethical Monitoring Reports. These reports will document issues related to research ethics that are relevant in DRIVER. The purpose of this questionnaire is to gather input from partners in order to guide the focus and content of the Ethical Monitoring Reports. You are kindly asked to fill in this questionnaire to the best of your knowledge and send it back to **stiber@prio.org** by **5th April 2016**.

As per the DRIVER DoW, the following partners are asked to give input: FOI, FHG, POLE, ATOS, ECORYS, MSB, JRC, FHG-IAO, ARC, DRC, ARMINES, Q4PR, FRQ, AIT, TCS, DLR, GMV, ITTI, EDI, MDA, THG, PSCE, ARTTIC, TNO

The information collected will be used for WP130 purposes only, and will not be shared with outside parties without permission. Personal information will be kept confidential. Please contact PRIO for any questions.

BASIC INFORMATION

- Name/ email:
- Organization:
- Main SP/ WP's:
- Main role in DRIVER (*end-user, solution provider, experiment leader, researcher, management, technologist, etc.*):

PRINCIPLES FOR ETHICAL RESEARCH

1. **For DRIVER, have you or your institution been in contact with local ethics committees or Data Protection Authorities?**
   a) If yes: describe shortly the process, did you encounter any (unforeseen) problems or challenges (e.g. lack of answer, unclear guidelines, or unclear responsibilities)?

   b) If no: do you foresee any particular problems or challenges in relation to obtaining appropriate approvals? Please describe.

2. **Did you, or do you plan to, make use of the template for "Application for Research Ethics Approval" provided by ex-SP9 in D91.3?**

3. **Are you missing any information with regards to research ethics? E.g. templates or guidelines on particular issues?**

4. **Have any ethical issues come up for your work in DRIVER that you have not experienced before?**

HUMAN PARTICIPANTS

5. **Do you do research including vulnerable groups (e.g. disabled, elderly, minors)?**
   a) If yes: how are you taking special precautions to ensure their well-being and to minimize harm?

6. **Will your research activity/ experiment affect the public in any way? If so, please explain (e.g. are bystanders exposed to the activity/ experiment; are you unable to inform everyone in the close surroundings of what is taking place; etc.)**

7. **Are individuals participating in the research activity/ experiment at risk of being harmed either physically (unsafe working environment, etc.) or psychologically (disproportional stress, discomfort, etc.)? Explain why/ why not.**

INFORMED CONSENT

8. **Did you, or do you plan to, make use of the informed consent template provided by ex-SP9 in D91.3?**

9. **Do you foresee, or did you have, any problems relating to informed consent (e.g. participants might feel obliged/pressured to participate in the activity/ experiment)?**

10. **For the experiments that you are involved in: are you able to give complete information about the activity to the participants beforehand or does the nature of the activity require you to partly withhold information? If so, please explain**.

INTERACTION WITH WP130

11. **How can PRIO (in WP130 "Research Ethics, Scientific support, IPR & legal issues") make it easier for you to do deal with the ethics issues in your research? (E.g. are you missing a certain kind of information or support? Do you want information/support in a different format?)**

12. **Are there any ethical issues you would like PRIO to bring forth to the DRIVER Societal and Ethical Advisory Board?**

OTHER (ETHICS) ISSUES

13. **Is there anything else relating to research ethics in your work in DRIVER you would like to share?**

Thank you for your cooperation!