Driving Innovation in Crisis Management for European Resilience

D913.14 – ETHICAL MONITORING REPORT 4

SP91 - PROJECT MANAGEMENT

JUNE 2019 (M62)

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The DRIVER+ project

Current and future challenges, due to increasingly severe consequences of natural disasters and terrorist threats, require the development and uptake of innovative solutions that are addressing the operational needs of practitioners dealing with Crisis Management. DRIVER+ (Driving Innovation in Crisis Management for European Resilience) is a FP7 Crisis Management demonstration project aiming at improving the way capability development and innovation management is tackled. DRIVER+ has three main objectives:

1. Develop a pan-European Test-bed for Crisis Management capability development:
    a. Develop a common guidance methodology and tool, supporting Trials and the gathering of lessons learnt.
    b. Develop an infrastructure to create relevant environments, for enabling the trialling of new solutions and to explore and share Crisis Management capabilities.
    c. Run Trials in order to assess the value of solutions addressing specific needs using guidance and infrastructure.
    d. Ensure the sustainability of the pan-European Test-bed.
2. Develop a well-balanced comprehensive Portfolio of Crisis Management Solutions:
    a. Facilitate the usage of the Portfolio of Solutions.
    b. Ensure the sustainability of the Portfolio of Solutions.
3. Facilitate a shared understanding of Crisis Management across Europe:
    a. Establish a common background.
    b. Cooperate with external partners in joint Trials.
    c. Disseminate project results.

In order to achieve these objectives, five Subprojects (SPs) have been established. **SP91** ***Project Management*** is devoted to consortium level project management, and it is also in charge of the alignment of DRIVER+ with external initiatives on Crisis Management for the benefit of DRIVER+ and its stakeholders. In DRIVER+, all activities related to Societal Impact Assessment are part of **SP91** as well. **SP92** ***Test-bed*** will deliver a guidance methodology and guidance tool supporting the design, conduct and analysis of Trials and will develop a reference implementation of the Test-bed. It will also create the scenario simulation capability to support execution of the Trials. **SP93** ***Solutions*** will deliver the Portfolio of Solutions which is a database driven web site that documents all the available DRIVER+ solutions, as well as solutions from external organisations. Adapting solutions to fit the needs addressed in Trials will be done in **SP93**. **SP94** ***Trials*** will organize four series of Trials as well as the Final Demo (FD). **SP95** ***Impact, Engagement and Sustainability***, is in charge of communication and dissemination, and also addresses issues related to improving sustainability, market aspects of solutions, and standardisation.

The DRIVER+ Trials and the Final Demonstration will benefit from the DRIVER+ Test-bed, providing the technological infrastructure, the necessary supporting methodology and adequate support tools to prepare, conduct and evaluate the Trials. All results from the Trials will be stored and made available in the Portfolio of Solutions, being a central platform to present innovative solutions from consortium partners and third parties, and to share experiences and best practices with respect to their application. In order to enhance the current European cooperation framework within the Crisis Management domain and to facilitate a shared understanding of Crisis Management across Europe, DRIVER+ will carry out a wide range of activities. Most important will be to build and structure a dedicated Community of Practice in Crisis Management, thereby connecting and fostering the exchange of lessons learnt and best practices between Crisis Management practitioners as well as technological solution providers.

Executive summary

This report is the fourth and final Ethical Monitoring Report delivered in the DRIVER+ project. It aims to describe and reflect issues relating to research ethics that PRIO as leader of **WP913** ***Research Ethics & Societal Impact Assessments*** is responsible for monitoring. The report covers the main issues that have been relevant within the reporting period that it covers (M50-M62) but it also provides some broader reflections on issues that have been discussed during the project as a whole. Some issues are new, others have been reflected in previous reports, but are still valid and relevant. In general, the report follows a similar setup as the three previous reports. As with the third report (**D913.13** ***Ethical Monitoring Report 3***) (1), some changes were made based on lessons learned from writing the first three reports. These changes mainly pertain to decisions taken to make the process of screening the project in preparation for this report more efficient and effective. These changes are implemented also in this final report.

Based on the insights informing this report (derived from various sources explained in Section 1.2), no critical issues relating to research ethics have been identified for the DRIVER+ project, but some issues have been identified, that should be followed up during the rest of the project. These issues are described throughout this report. None of the partners providing input to **D913.14** ***Ethical monitoring report 4***, via the ethical monitoring questionnaires, reports that there are any issues they want **WP913** ***Research Ethics & Societal Impact Assessments*** to bring forth to the DRIVER+ Ethical and Societal Advisory Board (ESAB), but the content of this report will form the basis for the next and final meeting of the ESAB late 2019.

The report is structured around five main sections. As for the previous reports, the introductory section shortly describes the fundamental importance of research ethics and puts this report into a larger context. It also states the limits and sources of this report. Section 2 summarizes and analyses the lessons learned in terms of research ethics throughout the project (2014-2019). Particularly, as part of this section, section 2.3 contains an overview of all recommendations and advice given in previous reports. The implementation of GDPR as of 28/05/2018 was given focus in **D913.13** ***Ethical Monitoring Report 3*** (1). Section 3 is an update on the implications of GDPR on DRIVER+, while section 4 focuses on the research ethics and data protection in the context of the DRIVER+ Trials. Section 5 provides some concluding remarks on **T913.1** ***Procedural ethics***.

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List of Acronyms

Acronym	Definition
AB	Advisory Board
CM	Crisis Management
CoE	Centre of Expertise
CoW	Community Workspace
CMINE	Crisis Management Innovation Network Europe
DoW	Description of Work
DPA	Data Processing Agreement
DR	Dry Run
ESAB	Ethical and Societal Advisory Board
FP7	7th Framework Programme for Research and Technological Development
GDPR	General Data Protection Regulation
NDA	Non-Disclosure Agreement
PM	Person Month
PoS	Portfolio of Solutions
SC15	Special Clause 15
SIA	Societal Impact Assessment
SP	Subproject
TAP	Trial Action Plan
TGM	Trial Guidance Methodology
TIM	Technical Integration Meeting
WP	Work Package

1. Introduction

This report is the fourth and final report of a line of Ethical Monitoring Reports that have been published throughout the DRIVER/DRIVER+ project. The aim of the reports, including this current report, has been to monitor and systematically screen the project with regards to emerging ethical issues, as well as to serve as key vantage points for the meetings between PRIO and the Ethical and Societal Advisory Board (ESAB). With this final report, task leader PRIO will summarize and reflect upon the key ethical issues that have emerged throughout the project, as well as anticipate and suggest some potential ethical issues that might emerge in the future, i.e. beyond the scope of the project. The recommendations presented in this report are foreseen valid for the rest of the project duration, and it is encouraged to take them into account for the remaining project activities.

To briefly summarize, the main issues that have been discussed and addressed as part of **T913.1** ***Procedural ethics*** have revolved around various issues relating to data protection and privacy. With the introduction of GDPR in midst of the project, these topics gained renewed attention, although they have been the key issues from the very beginning of the project. The importance of these topics has been underlined in every deliverable published as part of **T913.1** ***Procedural ethics***, as well as in the similar tasks and work packages in the previous phases and structures of the project. As anticipated in **D913.13** ***Ethical monitoring Report 3*** (1), for this final Ethical Monitoring Report, updates on ethical issues are documented, and relevant issues are discussed. Some repetition from previous reports will be evident, due to the fact that some issues remain relevant for this reporting period. In addition, as this current document is the final report of this kind for the project, a section summarizing and reflecting upon the present and previously emerging ethical issues for the project as a whole has been added.

1.1 The Fundamental Importance of Research Ethics

Research ethics can be defined in several ways, but generally refers to "a diverse set of values, norms and institutional regulations that help constitute and regulate scientific activity" (2). Further, it is a fundamental part of all levels and stages of the research process and the researcher must from the very beginning of the research activity consider ethical principles that will guide the activity. The European Code of Conduct for Research Integrity serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings (3). The 2017 revised edition of the Code addresses emerging challenges emanating from technological developments, open science, citizen science and social media, among other areas. The European Commission recognizes the Code as the reference document for research integrity for all EU-funded research projects and as a model for organizations and researchers across Europe. The Code was published originally in English on 24/03/2017 and was translated to all official EU languages by the European Commission's Translational Services and with the support of ALLEA Member Academies[1].

The document is based on the acknowledgement of four central principles of research integrity, which have also been underpinning the work on research ethics in the DRIVER+ project, explicitly and implicitly. These are quoted in the following:

> *Good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical and intellectual challenges inherent in research. These principles are:*
>
> - *Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.*
> - *Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.*

[1] More information about this document, as well as versions of the document in all official EU languages can be found on this page: https://www.allea.org/publications/joint-publications/european-code-conduct-research-integrity/

- *Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.*
- *Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts* (3).

The Norwegian National Ethics Committee has also developed a set of general guidelines with four fundamental principles to follow in order to conduct the research activity in an ethically sound manner (2). The overall guiding principles to follow are *respect*, *good consequences*, *fairness* and *integrity*. *Respect* refers to a respectful treatment of all people involved in the research activity. In relation to this, it is important to treat the personal information of people involved in a study with confidentiality to avoid that personal information is used to inflict damage on the people involved. To put this more explicitly, the research activity must produce *good consequences* and limit the adverse consequences to a strict level of acceptability. The production of good consequences can also mean to ensure that the result of the research activity has benefits not only for the ones involved in the research, but also for society in general.

In crisis management in general, and in DRIVER+, this could be the better implementation of tools and solutions that helps to foster resilient communities, or the development of assessment frameworks for societal impact. *Fairness* refers to the very act of designing and implementing the research activity in a fair manner. Last, the research activity must be implemented in a way that shows *integrity* of both the research activity, but also the researcher(s) that conducts the activity. This can be achieved through complying with recognized norms and at the same time act responsible, openly and honestly. Any falsification, fabrication of results or plagiarism will lower or take away the integrity of the research (3). In the area of norms, it is important to take into consideration national laws and regulations and international conventions and agreements that may have implications on the research activity, and to follow these. If the researcher fails to follow these principles, it will affect the overall quality of the research and can in the worst-case lead to the research activity to be stopped. While the values, norms and regulations that regulate research ethics, also in the context of DRIVER+, have been emphasized in deliverables and presentations throughout the project duration, they remain highly relevant for this reporting period. Not because there have been significant breaches identified, but because the considerations remain the same also for upcoming research activities.

On a higher level, since research ethics is a fundamental part of research projects such as DRIVER+, it has been part of the foundation on which the project was initially built. In general, the consortium partners are obliged to describe and expect ethically relevant issues for the proposed project already at the stage of developing and submitting project proposals to the various EU funding channels, such as the current H2020 or the previous FP7, under which DRIVER+ was funded. At the proposal stage, the partners are expected to demonstrate how various ethical issues will be considered and handled in the proposed project. DRIVER+ was funded under FP7 and included research ethics as a distinct administrative part of the project since its development. For projects funded under the current H2020, the topic is still given much attention. Specifically, Article 19 of Regulation (EU) No 1291/2013 establishing Horizon 2020 (4) describes the basic ethical principles. Article 34 of the Annotated Model Grant Agreement describes the basic ethical principles that are based on ten main ethical principles (5). These must be addressed as relevant to the research activity in the project:

Article 34 GA Ethics – Main ethical principles

- Respecting human dignity and integrity.
- Ensuring honesty and transparency towards research subjects and, notably, getting free and informed consent (as well as assent whenever relevant).
- Protecting vulnerable persons.
- Ensuring privacy and confidentiality.
- Promoting justice and inclusiveness.
- Minimising harm and maximising benefit.

- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries.
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research.
- Respecting and protecting the environment and future generations.
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

Research ethics can certainly encompass many different considerations and activities. In the context of DRIVER+, research ethics has been mainly about privacy and data protection-related issues. This is reflected also in the previously submitted ethical monitoring reports. The attempts to systematically integrate research ethics into research projects funded by the EU that take different shape, but they share some commonalities as well, as described e.g. in section 2 of **D913.31** ***Societal Impact Assessment- version 2*** (to be submitted in M63).

1.2 Sources of information for the Ethical Monitoring Report

Similar to the first Ethical Monitoring Report (**D95.31**) (6), and the second (**D130.42**) (7) and the third Ethical Monitoring Report (**D913.13**) (1), the input to this report is derived from different sources: 1) questionnaires filled out by all the SP-leaders required to give input as per the new DRIVER+ DoW.[2] The returned questionnaires cover all Subprojects, and the SP-leaders were given the option of either answering the questionnaire on behalf of the WP's in the SP or to solicit input from the WP leaders (PRIO recommended the latter), 2) reflections from the fourth DRIVER+ Ethical and Societal Advisory Board meeting, which held its fourth meeting of the project together with the regular AB meeting in Copenhagen, Denmark in June 2019, 3) Issues relating to research ethics which has become apparent to PRIO as leader of **WP913** ***Research Ethics and Societal Impact Assessments*** and the consequential tasks and responsibilities within the WP, and 4) the deliverable finally also repeats, refines and reflects upon some core points from previous ethics deliverables, since this is the final deliverable of the project on research ethics.

The ambition is that this final Ethical Monitoring Report can provide a more comprehensive account of research ethics as a whole for the project, by e.g. providing references to where information and guidelines on the most important issues can be found in previously submitted reports. As a way to facilitate this, the current report includes also an overview of the most relevant ethical issues that have emerged throughout the project. This overview, based on an analysis of all previously submitted ethics deliverables by **WP913** ***Research ethical and societal impact assessments*** leader PRIO, can be found in section 2.3. As for the previous report, the submitted report will be shared with the consortium, to remind all partners of their obligations and of the role of PRIO as leader of **WP913** ***Research Ethics & Societal Impact Assessments***.

1.3 Structure of the Deliverable

The report is structured around five main sections. As for the previous reports, the introductory section shortly describes the fundamental importance of research ethics and puts this report into a larger context. It also states the limits and sources of this report. Section 2 summarizes and analyses the lessons learned in terms of research ethics throughout the project (2014-2019). Particularly, as part of this section, section 2.3 contains an overview of all recommendations and advise given in previous reports. Section 3 is an update on the implications of GDPR on DRIVER+. Section 4 focuses on the research ethics and data protection in the context of the DRIVER+ Trials. It also provides an update on the integration of research ethics into the Trial

[2] The key issues described in the questionnaires are reflected in this report, and the collected questionnaires can be retrieved from PRIO upon request, e.g. by the PO or the ESAB. The fact that not every detail on information from the questionnaires are described in this report does not mean that PRIO is not following up on the identified issues.

Guidance Methodology. Section 5 provides some concluding remarks on the status of **T913.1** ***Procedural ethics***.

1.4 The scope and limitations of the DRIVER+ Ethical Monitoring Report 4

The content of this report compliments the content of the previous three Ethical Monitoring Reports. In the instances where it is presented with some repetition, this is due to the fact that some topics and some recommendations have still been relevant in the reporting period that this report covers. The report also compliments **D913.12** ***Ethical approval*** (8), which was a deliverable created to discuss ethical issues in relation to the Trials. As with the second and third version of this report, the purpose 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 **T913.1** ***Procedural Ethics***, 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 more significant risks to the project should they not be addressed.

The deliverable does not aim at summarizing *all* ethical issues since the last report was submitted in June 2018 (M50), but rather to focus on the state of the project at this point, and its final phase. Summaries of all the key issues, including templates and a list of recommendations are still available under "Ethics tiles" on the CoW. In addition, research ethics is increasingly integrated into the Trial Guidance Methodology (TGM), and a final version of the TGM (from a research ethics point of view) will be ready in M64. Although this is the final Ethical Monitoring Report of the project, the work on ethics does not stop here. As part of the 5th amendment to the DRIVER+ Grant Agreement, **T913.1** ***Procedural Ethics*** have been boosted with 2.5 additional PM's and extended until M70, so that the work in this task can continue until the end of the main project activities, for example to follow up on the issues described in this report.

2. Lessons learned throughout DRIVER+

The following section provides an overview of recurring and central ethical issues to the DRIVER+ project since the beginning of the project. It is based upon the three Ethical Monitoring Reports, **D95.31** ***Ethical monitoring report 1*** (6)***, D130.42 Ethical monitoring report 2*** (7) and **D913.13** ***Ethical monitoring report 3*** (1)**,** and it presents the overarching, general and fundamental ethical issues that have been part of the project since the beginning and until M62. The summary is not to be seen as a collection of all relevant ethical issues in the project, but as a summary of key issues that are foreseen to be relevant also for the future of the DRIVER+ legacy beyond the scope of the project.

A general lesson learned is that there has been some confusion among the project partners with regards to the scope of the tasks and the responsibilities of **WP913** ***Research ethics and societal impact assessments***. Despite the active effort during the restructuring of the project during the suspension phase to distinguish clearly between the task of following up on research ethics in **T913.1** ***Procedural ethics*** and developing a methodology for doing societal impact assessments in **T913.3** ***Societal Impact Assessment Framework*** and the related tasks, the two streams of work are often referred to in the same breath and sometimes confused. This has not posed any major challenges, but a lesson learned is that the administration of the tasks such as those making up **WP913** ***Research ethics and societal impact assessments*** should be ever clearer defined. Partly, this can be understood by looking at the rather wide description of research ethics that the project has based its work upon (ref. section 1.1 of this report).

In the ethical monitoring questionnaires for **D913.14** ***Ethical Monitoring Report 4***, the question was asked: "Looking back on the project as a whole, what has changed since the beginning of the project? Did you learn something new regarding research ethics? What have been the main challenges?". There were different views on this, and one partner reported that they have learned something about ethical research principles like openness and honesty, carefulness, objectivity, e.g. fair selection of solutions in Trials, informed consent and usage policies for the PoS, CMINE, etc. Others report that they have not experienced specific issues in their activities, but that the implementation of GDPR has represented a challenge for them and their organizations, e.g. for communication purposes. Specifically, "Sometimes it was not clear what to do and how to apply such rules within a European funding project". Others reported that the templates provided by PRIO have been clear, and that there has been available support from PRIO whenever necessary.

2.1 Key issues 2014- 2019

Based on a screening and an analysis of the previous three Ethical Monitoring Reports, the main ethical issues identified between 2014- 2019 are summarized into four categories, which are not mutually exclusive: (1) privacy and data protection, (2) informed consent, (3) the project's impact on the public and volunteers, and (4) GDPR.

2.1.1 Privacy and data protection

Privacy and data protection remain the most important issues within the DRIVER+ project, also in this final reporting period. **D95.31** ***Ethical Monitoring Report 1*** (9) provides information about the relevance of privacy, personal data and data protection approvals in the project and describes in detail why it is a fundamental part of good research ethics. The topic is also thoroughly discussed in **D130.42** ***Ethical Monitoring Report 2*** (7) and **D913.13** ***Ethical Monitoring Report 3*** (1). It was stated in several of these reports that many of the research activities foreseen and planned in the DRIVER+ project such as interviews and, what was previously labelled "experiments", would become subject to approvals regulated by Special Clause 15. This meaning that the task leaders would need to seek approval from local ethics committees or Data Protection Authorities in advance in order to conduct the research activity. To some extent this became the case, and many such approvals (or applications) have been collected by PRIO in the deliverables in **T913.1** ***Procedural ethics***. However, there have been no identified instances where there have been significant problems relating to this.

A key issue has also been the fact that the DRIVER+ project, to some extent, goes beyond traditional desk-research and workshops and includes research participants external to the project such as volunteers. **D95.*31 Ethical Monitoring Report 1*** (9) showed that the majority of the partners that were asked to provide input to the report had been in contact with local ethics committees or DPAs and that the process was perceived to be straight forward. The same feedback was given in **D130.42 *Ethical Monitoring Report 2*** (7). Within the current reporting period (M50-M62), no partners reported to have been in contact with such authorities.

D95.31 *Ethical Monitoring Report 1* (9) discovered that there were partners within the project that did not have any experience with research ethics. Because of this, guidelines on ethics were produced by PRIO (10) with this in mind, for example, including checklists and basic guidance on key issues. Some partners reported that the issue of ethical approval was a new one and others reported that they felt research ethics rules and recommendations had become stricter, based on experience from previous work. In **D95.31 *Ethical Monitoring Report 1*** (9), it was apparent that there was some confusion on whether to seek approval from DPA or ethical boards or committees. A table was made to facilitate the question whether data protection approval is needed or not in order to conduct the activity, and can be found on page 11 of the report.

A topic that also was new to some of the partners was the handling of what might be defined as sensitive data. Sensitive data is often important in crisis management and was therefore anticipated to be a natural part of the DRIVER+ project. It was stated that if it turned out to be the case that sensitive data were to be collected, such as sex, health status, religion and nationality, this activity would require some special attention. For example, it was made clear that it should be specified in the informed consent if sensitive data is to be collected. Depending on national legislation and guidelines from the national DPA, it is likely that there are rules that specifically concerns how sensitive data should be taken care of. This can for example be that sensitive data must not be stored together with normal personal data or that special security measures must be taken for storing it safely. All partners facing the eventual collection of sensitive data were encouraged to get in contact with PRIO directly, so that the eventual challenges could be solved jointly.

One very concrete ethical issue in the area of data protection which was both represented in **D95.31 *Ethical Monitoring Report 1*** (9) and **D130.42 *Ethical Monitoring Report 2*** (7) was the use of UAVs in the activities of the project. Because several European countries at the time of the publishing of **D95.31 *Ethical Monitoring Report 1*** (9) did not have particular regulations on the use of UAV's, it was argued that the images from the UAV (in the event that they were to be used within the project) should only be used to distinguish between humans and non-humans, and the picture should only be as detailed enough so that the viewer could see whether the person shown needed assistance or not. The question of UAV's was also discussed in **D130.42 *Ethical Monitoring Report 2*** (7) in relation to data storage, and it was discussed how it is the task leader of the country where the data is stored who is the one that needs to seek data protection approval although the images might be from another country.

Within the reporting period that this final Ethical Monitoring Report covers, none of the partners report that they have been in contact with local ethics committees or Data Protection Authorities. One partner reports that such contact might be foreseen for future activities, i.e. that data protection requirements will have to be taken into account as soon as the Centre of Expertise (CoE) concept will take shape. This would entail, e.g., the transferability of some key Test-bed outputs such as the training modules, and that "learners" will register to an online platform. The way in which personal data will be collected will have to be discussed in more detail at a later point in time. In addition, one partner specified that they have been working actively to adapt the activities to the GDPR requirements for more than a year, and that there are some ongoing activities that will need to actively "respect data protection requirements". Finally, one partner reported that they had been in contact with another partner's internal services for discussing an ethical issue relating to Trial 2. PRIO was also contacted regarding the same issue, and provided the partners involved with a written report with recommendations and guidance. This exchange was documented in **D913.12 *Ethical approval (Ethical issues and lessons learned for Trials)*** (8).

The template for "Application for Research Ethics Approval", prepared by PRIO, has not been used within the reporting period. This is because of reasons such as the changing requirements as per GDPR ,or the fact that many partners do not actually conduct research activities per se. No partners report that they are aware of any plans to use it for future activities.

In the ethical monitoring questionnaires for **D913.14** ***Ethical Monitoring Report 4,*** no partners reported that they have faced any issues relating to data protection or research ethics that they have not experienced before. In the scope of the project activities, the questionnaires also asked if there are still challenges in your work that has to do with research ethics. No partners reported that this was the case. However, there have been some challenges with regards to the selection of solutions. The procedure for this has been improved to assure objectivity and transparency. For example, commercially sensitive evaluation data has been removed from public reports to avoid potential harm to solution providers. It is possible that on the level of specific solutions there might be ethical considerations, but the development of these solutions is not part of the project. Furthermore, various groups of people are (still) involved in the Trials, and will be in the remainder of the project, but no critical ethical challenges have appeared until M62.

2.1.2 Informed consent

One of the most central ethical issues in all the earlier reports has been informed consent. Informed consent is a general ethical requirement in research that involves human beings and has been a recurring topic for discussion since the beginning of the project. Informed consent was also part of the discussion in the beginning of the project related to "experiments" (which is the now abandoned term for some research activities that took place in the earlier phase of the project). The core of the discussion was, if potential activities should take place in public, there should be extra efforts made in providing information about what could happen to possible bystanders and other relevant people. In **D95.31** ***Ethical Monitoring Report 1*** (9) it was noted that it is not always possible to get full informed consent from participants in the experiments in advance. Sometimes the nature of the "experiment" does not allow the participants to know every single detail of it. To justify such withholding of information, the utility of the research must clearly exceed any disadvantage that may be inflicted on the participants.

Specifically, simulating through the use of scenarios was a significant part of what was called the DRIVER+ "experiments" in the early phase of the project. To not be able to give full insight in what the scenarios will consist of to the participants beforehand, was generally not considered to be a problem. In fact, to only provide the necessary amount of information to a participant in the simulation might be the only effective way to perform this kind of exercise, as an element of surprise is crucial to keep it realistic. The general rule is that if the nature of the activity allows it, informed consent should be collected before the activity. If not possible, it should be sought afterwards. This was also the advice from the ESAB on this matter.

The length of the information given for consent was also pointed out to be an issue in **D95.31** ***Ethical Monitoring Report 1*** (9) and **D130.42** ***Ethical Monitoring Report 2*** (7), especially in relation to the use of a mobile application. The worry was that if it is too long no one would read it, and if it is too short it might lack important information. By using a mobile application to collect the informed consent there is the risk that the participant will just tick all the boxes in the scheme without reading it properly. In **D913.13** ***Ethical Monitoring Report 3*** (1), it was stated that this is less of a concern after the implementation of the GDPR, but that it would enhance the quality of the research if the informed consent is collected through printed signs or informative posters as this would provide more information.

Another concern with the length of the text was that the responders felt that using an informed consent form is an extra burden upon the volunteers because it takes extra time than just having to participate in the research activity. The fear was that this requirement could discourage participants from participating. **D130.42** ***Ethical Monitoring Report 2*** (7) takes up this issue, and states that even though this extra paperwork for the participants might be understood as "annoying", it is a task that is fundamental to reach the best practice for research ethics, and participants in research activities need to be informed clearly

about the activities they are participating in, and consent to these activities. This is of clear mutual benefit- both for the researcher(s) and the participant(s).

Another key issue related to informed consent has to do with language acquisition, meaning that the information given to the participants might need to be written in the native language of participants. It is necessary that the participant fully understands the provided information in order to give informed consent. To provide information in the native language might therefore be necessary in some of the research activities, especially when participants are not fluent in English or does not understand it well enough. The organizers of such activities should realize that participants might feel embarrassed or unconformable stating that they don't understand, and thus should the threshold for offering informed consent forms in the native languages be set quite low. **D913.13** ***Ethical Monitoring Report 3*** (1) adds that the topic of language was also raised in the Workshop "0" which was held in Warsaw prior to Trial 1. There it was stated that the documents to be provided to external participants in the Trial should be provided in plain language and with the use of easy English-language formulations.

Table 2.1: Minimum requirements for informed consent

Basic requirements for informed consent	Consent must also be…
The data controller's identity.	Informed, freely given and specific.
What kind of data will be processed?	Bound to specific purposes that are explained.
How the data will be used.	Preferably written.
What the purpose of the processing is.	In clear and plain language.
A statement that the consent can be withdrawn.	Unambiguous and explicit

In Table 1, an overview of the minimum requirements for informed consent is summarized. Further information on the topic can be found in section 2.1 of **D913.12** ***Ethical approval*** (8). There, the issue of informed consent in relation to the DRIVER+ Trials is more extensively discussed.

In the ethical monitoring questionnaires for **D913.14** ***Ethical Monitoring Report 4***, the question was again asked if the templates provided by PRIO were used and deemed relevant. Regarding the template for obtaining "Informed consent", some partners reported that they have used the template within the reporting period, e.g. for the involvement of external solution providers and practitioners in the DRIVER+ Trials (Trial 2 and Trial 4). There have been no issues with using the form, but for the visitor's programme held during the Trial in The Hague a shorter version was used, only covering consent for recordings and photography. Considering that the involvement of those visitors was so limited it was judged that a shorter, simpler consent form was enough. For Trial 2, a specific consent form was used for some activities regarding the upload of pictures to one of the solutions used in the Trial. For Trial 4, one partner reports how they worked together with PRIO to develop a form that was used for participants in TIM, DR1, DR2 and the Trial. This template is available on the CoW and will also be used for the Austrian Trial (including new people participating in the Trial preparation meetings) and the activities surrounding the Final Demo.

2.1.3 The project's effect on the public and volunteers

In **D95.31** ***Ethical Monitoring Report 1*** (9), there was one ethical issue connected to planned "experiments" in the project that could affect the public. For large-scale experiments or field experiments there was the possibility that bystanders might decide to join the experiment, and what implications that might have for them and for the project. The key ethical issue in this case was how to share information with such participants so that informed consent can be obtained. However, this theoretical concern turned out not to be an issue in the executed Trials.

D95.31 ***Ethical Monitoring Report 1*** (9) also notes that crisis managers rarely know much about the volunteer or participant in the exercise/experiment. If the exercise concerns a scenario which is graphic, disturbing or have the potential of evoking strong negative emotions, a person dedicated to following up

eventual reactions and follow up with the relevant people should be present and should be made known to participants. De-briefs after such eventual activities were seen as useful and relevant. All research activities which tests human reactions should be well thought-through and follow ethical guidelines. **D130.42** ***Ethical Monitoring Report 2*** (7) states that most of the activities are taking place in closed environments with volunteers and that this had not been an issue.

D95.31 ***Ethical Monitoring Report 1*** (9) states that it is difficult to assess whether the project will inflict harm on participants as the experiments had yet to start. It was anyhow acknowledged that there must be included some stress for the experiment to be realistic. This is especially relevant in the inclusion of vulnerable groups. For example, for vulnerable group such as refugees, talk of crisis can be a trigger for trauma related to the reasons of their migration. **D95.31** ***Ethical Monitoring Report 1*** (9) notes that the process of labelling a person or a group as "vulnerable" might in itself invoke negative reactions. The risk of this happening is enforced if the individuals are not recruited from a group or association where the "vulnerability" is the common trait of the members and it is therefore considered to be best-practice to recruit individuals from such groups and organizations. There must be taken particular care that the rights of the vulnerable groups are protected and that their participation in the project is voluntary and based on informed consent.

In **D130.42** ***Ethical Monitoring Report 2*** (7), most respondents replied that their activities do not involve such vulnerable groups. Further, none of the respondents to the ethical monitoring questionnaire reported that the participants in the research activity are at risk of being harmed, either physically or psychologically. This was because the activity played out a scenario that was well-rehearsed and familiar to the participants. The report also quotes one of the respondents in saying that experienced volunteer managers from professional responder organizations will take care of the safety of volunteers.

2.1.4 GDPR requirements relevant for DRIVER+ Trials

As iterated also in previous reports, the implementation of the GDPR represents a challenge for each individual partner, and the responsibility for ensuring legal compliance from a business point of view lies with each legal entity/project partner. PRIO is neither responsible nor capable of ensuring GDPR compliance for all DRIVER+ partners. While PRIO is tasked to assist in specific cases or with specific questions, the responsibility of PRIO has been to ensure that the personal data collected, processed and shared within/by the project are handled in such a way that it protects the privacy of the data subjects. These data subjects are e.g. volunteers participating in the Trials or external solution providers. Templates regulating their participation, as well as potential collection of personal data that necessitates approval by data protection authorities (e.g. informed consent forms and ethical approval) have been prepared by PRIO and can be found on the CoW.

An extensive section called "Implications of the GDPR on DRIVER+ and WP913" was already included in section 2 of **D913.13** ***Ethical Monitoring Report 3*** (1), and this information will not be repeated in detail here. The section summed up the key implications of the GDPR in general, and on DRIVER+ activities in particular. Parts of the section were derived from section 5 of **D922.21** ***Trial Guidance Methodology and Guidance Tool Specifications (version 1)*** (11), where some general guidance and suggestions for implementation of research ethics requirements into the Trial Guidance Methodology was already provided. However, the section went more into detail, and attempted to specify the GDPR requirements, especially as they were relevant for the upcoming Trials.

The main GDPR principles and requirements listed in section 2 of **D913.13** ***Ethical Monitoring Report 3*** (1) were the following:

- Lawfulness, fairness and transparency.
- Collection, processing and purpose limitations.
- Data minimization.
- Accuracy.
- Storage limitations/integrity and confidentiality.

In section 2 of **D913.13** ***Ethical Monitoring Report 3*** (1), the bullet point list contained detailed requirements that were structured according to the different phases of the TGM, i.e. preparation, execution, and evaluation. This list remains valid and crucial to all research activities for the rest of the DRIVER+ project. In the ethical monitoring questionnaires informing **D913.14** ***Ethical Monitoring Report 4***, PRIO asked the question "In which way are the new EU General Data Protection Regulation (GDPR) requirements reflected upon in your institution's DRIVER+ activities? Are you aware of any challenges that partners have within the SP/ WP, with regards to adhering to the new requirements?". Several partners reflected on this, by explaining how their organizations have adapted to meet the GDPR requirements, and only one partner reported that they have had some GDPR-related problems. This had to do with some problems getting in touch with a DRIVER+ partner because a contact list was not available any longer, but this issue is presumed solved already a while ago. Others report to be aware of challenges, but that they are not really relevant, for example because the activities were completed before the new regulation came into force, or because the organization has established a data controller who is made aware of the activities in DRIVER+, but has no problems adhering to the new requirements.

2.2 Summary of advice and recommendations given throughout DRIVER+

Based on the summaries in section 2.2 of this report, an overview of the most relevant recommendations given by PRIO, in relation to the ethical issues emerging throughout the project, can be found in Table 2 below.

Table 2.2: Summary of advice and recommendations given throughout DRIVER+

Issue	Recommendations
Research activities with human participants.	• Collect informed consent from the participant. • Notify or collect approval from the relevant ethical committee or Data Protection Authority, if relevant.
Informed consent from the public (e.g. bystanders) in research activities taking place in the field.	• Before the activity: If possible, informed consent should be collected. • Before the activity: Provide information by handing out flyers describing the activity, announcing it on local radio, ads in the local newspaper and notifications on information boards in the surrounding area. • After the activity: If not possible in advance, informed consent should be collected after the data collecting activity.
Informed consent from volunteers and participants.	• Provide clear and accurate information, without compromising the foundation or aim of the methodology. • Information sheets and informed consent sheet should be distributed to all external participants minimum two weeks before they are involved in the research activity.
Informed consent from vulnerable groups (i.e. people with disabilities, elderly, migrants, etc.).	• Particular care must be taken to ensure that the rights of vulnerable groups are protected and that their participation is fully voluntary and informed. • Check local / national guidelines for particular rules.
Inclusion of minors in research activities.	• This should always be discussed with PRIO (within the scope of DRIVER+), the relevant (local) DPA and/or Ethics Committee.

Issue	Recommendations
The role of the volunteers and/or actors.	• Before the activity: Information on their expected behaviour, verification of relevant conditions about the volunteer (i.e. allergies, claustrophobia), and an active and voluntary consent must be in place. • During the activity: Provide them with a contact person that can answer question they might have. • After the activity: Volunteers should take part in the evaluation of the exercise and in case of injuries or traumatic experiences, a responsible tactical and psychological debrief should be organized.
What is defines as personal data?	• The definition from General Data Protection Regulation (2016/679) should be followed[3].
Mitigate the risk of breaching the data subject's privacy.	• Define a clear purpose for the data collection and ensure clear rules for data minimization, deletion and physical protection. • Do not collect any data that you do not need in connection to the principle of data minimization. • Do not store personal data longer than the need for the specific purpose.
Consider if a Privacy Impact Assessment (PIA) is relevant.	• Perform an assessment of potential privacy implications as early in the process as possible. • Consider who within the organization is most suited to assess privacy implications. • Identify the issues to be assessed (i.e. rules and routines for data collection, processing or sharing of personal data). • The assessment must not compromise the internal interest of the organization. • Document that a privacy impact assessment has taken place.
Collecting visual recordings (photo or video).	• Add information if visual recordings will take place during the research activity to the informed consent form. • State clearly how the images will be stored and used. • Do not use photos or video recording for other purposes for which it was taken. • When photographing a large group, ask the individuals appearing on the photo verbally for permission. • When photographing a small group, best practice would be to seek approval before the image is captured.

In the ethical monitoring questionnaires informing **D913.14** ***Ethical Monitoring Report 4***, PRIO asked the question "As part of the activities in your SP/ WP, have any emerging issues relating to research ethics been identified since the last ethical monitoring report (M50 - June 2018)? If so, how are they being tackled?". None of the partners reported that this was the case.

[3]D95.31 Ethical Monitoring Report 1 and D130.42 Ethical Monitoring Report 2 referred to the definition of personal data from EU Data Protection Directive (95/46/EC).

3. Update on the implications of GDPR on DRIVER+ and WP913

When GDPR came into effect in May 2018 it imposed obligations on all organisations that process personal data of EU citizens. Although the GDPR is not designed to target research activities specifically, it still affects all research activities that process personal data and is therefore relevant to DRIVER+. The definition of scientific research purposes in GDPR is to be interpreted in broad terms including "technological development and demonstration, fundamental research, applied research and privately funded research"[4]. The most important changes for research with the implementation of GDPR is that when personal data is collected for research purposes, the organisations collecting them might avoid restrictions on secondary processing and on processing sensitive categories of data[5].

One way that personal data is processed for research purposes in DRIVER+ is by collecting an informed consent from the data subject. In GDPR and through good research ethics, the consent must be freely given, specific, informed and unambiguous[6]. Under the GDPR it is however stated that "[…] it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of collection"[7]. In addition, article 6(4) allows for subsequent processing operations that are compatible. Research purposes are understood to be compatible with further processing[8]. Article 5(1)(b) states, "further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes."

Participants should be given the information they need and no more, in a concise and clear way. There is a trade-off between detail and comprehension on the part of the participant. Informed consent must be collected, and confidentiality of data ensured. Further implications are that within research, organisations may override a data subject's right to object and to seek the erasure of personal data[9], if appropriate safeguards are implemented. Article 89 sets out the safeguards that must be implemented in order to process personal data for scientific research. Researchers applying for EU grants under the Horizon 2020, report that ethical assessments have become more extensive since 2018[10]. In addition, privacy rights and research ethics have in general attracted more attention since the implementation of the GDPR in May 2018.

Also relating to GDPR requirements was the substitution of the current CMINE Online Platform (www.cmine.eu) with a commercial alternative Hivebrite. This took place mainly in M62. PRIO was involved in discussions about both the Data Processing Agreement (DPA) and the privacy policy suggested by Hivebrite, and this discussion is partly referred in the remainder of this section.

Regarding the DPA, PRIO noted that the DPA is focused on stating that the legal responsibility of the processing of personal data lies with you/Customer, and not with Hivebrite, which is normal procedure, but not always obvious. In section 2.4 (i), it states that informed consent should be sought in advance of data collecting activities. This means that for any personal data collected from people within the scope of DRIVER+, but that will be processed/stored beyond the project, consent needs to be sought again if the information is to be processed further. The rest of 2.4 (i) - (x) are basic, but very important principles of GDPR that should be given top priority in the view of PRIO. Point (i) - (viii) on page 4-5 lists what should be included in the privacy policy posted to the webpage. In page 6 under (iv), there is a long description of a processing audit, which comes with some obligations for the Customer (also financially). PRIO also notes

[4] Recital 159.

[5] Article 6(4); Recital 50.

[6] Recital 32.

[7] Recital 33.

[8] Recital 50.

[9] Article 89.

[10] See for example this report: https://www.etikkom.no/en/news/news-archive/2019/eu-has-become-stricter-researcher-wrote-eight-pages-on-ethics--waited-six-months-for-the-money/

that under section 2.9, the statement "The Customer hereby consents to the Processing of Personal Data by the sub-processors listed in Annex 2. The Customer gives a general authorization to Hivebrite to make any modification, change, addition or replacement of these sub-processors" means that Hivebrite can de facto decide to share the personal data with anyone, as long as they find it reasonable. A clarification on what kind of criteria could be deciding when eventually adding new sub-processors would be appropriate. For Annex 1, the list of the types of personal data processed is quite extensive (e.g. academic curriculum and results). It was not immediately clear to PRIO what this list means, i.e. what it is a list of.

Regarding the privacy policy, PRIO suggested that the task leader have a look at the GDPR webpage (https://gdpr.eu/privacy-notice/), which contains a very easy introduction to writing a GDPR-compliant privacy notice, including the basic requirements, the most relevant GDPR Articles, as well as a suggested template available for download. Although there is no reason to doubt that Hivebrite is not complying with the requirements, but maybe it could be worth double-checking against this template.

However, regarding format, the most important principles are that the privacy notice is:

- In a concise, transparent, intelligible, and easily accessible form.
- Written in clear and plain language, particularly for any information addressed specifically to a child.
- Delivered in a timely manner.
- Provided free of charge.

Regarding content, the following are to be considered minimum requirements that must be included in the privacy notice:

- The identity and contact details of the organization, its representative, and its Data Protection Officer.
- The purpose for the organization to process an individual's personal data and its legal basis.
- The legitimate interests of the organization (or third party, where applicable).
- Any recipient or categories of recipients of an individual's data.
- The details regarding any transfer of personal data to a third country and the safeguards taken.
- The retention period or criteria used to determine the retention period of the data.
- The existence of each data subject's rights.
- The right to withdraw consent at any time (where relevant).
- The right to lodge a complaint with a supervisory authority.
- Whether the provision of personal data is part of a statutory or contractual requirement or obligation and the possible consequences of failing to provide the personal data.
- The existence of an automated decision-making system, including profiling, and information about how this system has been set up, the significance, and the consequences.

4. Research ethics and data protection in the context of the DRIVER+ Trials

During the reporting period which this report covers (M50-M62), in order to report on emerging ethical issues arising from Trial 1 and Trial 2, a new deliverable was created, replacing **D913.12**, which had the original title **D913.12** ***Ethical Approval***, with the new title **D913.12** ***Ethical Issues and lessons learned for Trials*** (8). This document was submitted in M56. The deliverable documents and reflects upon some lessons learned on ethical issues related to the Trials (planning, execution and preparation). It summarizes Trial-related ethics discussions that are taking/have taken place between **WP913** ***Research Ethics & Societal impact assessments*** and the project partners and that are not captured in any other document.

This document therefore functions as an interim ethical monitoring report, focusing on the Trial context. It was created to serve as an additional reassurance to REA that the activities are monitored with regards to research ethics, especially since **WP913** ***Research Ethics & Societal impact assessments*** does not have any formal efforts to follow the Trial execution. Documenting these discussions was expected to be of added-value for the upcoming Trials, and for similar future activities beyond the project. The deliverable was structured around seven key identified issues:

- Informed consent.
- Having a dedicated legal/ethics expert for Trials.
- Use of data from social media (i.e. Twitter).
- Roles & objectivity.
- Data storage.
- Contribution from the H2020 data management plan.
- Safety of participants.

More information on each of these can be found in dedicated sections of **D913.12** ***Ethical Approval*** (8), and some of these issues are discussed in more detail in this current report.

4.1 Identified issues and challenges for the Trials (M50-M62)

In the following sections, the key research ethics issues that have been identified in relation to the DRIVER+ Trials, or during discussions relating to the Trials, will be presented.

4.1.1 Legal/ethics expert present during execution phase[11]

The statement that the responsibility for ensuring legal compliance from a professional point of view lies with each legal entity/project partner in charge of the activity, has been made several times during the project. Although there has been no budget for this in the current setup of the DRIVER+ project and the Trials, for future users of the DRIVER+ legacy, it might be worth investing in having a dedicated expert on legal and ethical issues. This issue was also raised by REA during the 6th technical review of the project. Some reflections on this are described in the following.

The role of this individual, which could also be externally hired with no stake in the Trial activities, could be to analyse the information entered in the Trial Action Plan (TAP), e.g. to see what kind of solutions have been selected, what format the Trial is planned to take (table-top, field Trial, etc.), if/how external participants/volunteers are involved, and to help with getting the right approvals/templates. In addition, the relevant national supervisory authority in the country where the Trial is taking place can be contacted for GDPR specific issues. Such a unit exists in all EU member states. Within the scope of the DRIVER+ project, the role of **WP913** ***Research Ethics & Societal impact assessments*** has been limited to research ethics in the sense of collecting the required authorizations and notification for project activities, as well as

[11] The first half of this section is cited from D913.12 section 2.2.

informing and advising project partners about research ethics. However, outside the context of a research project, it might be likely that an expanded role is necessary, and the idea of appointing a representative for these key issues seems sensible. Of course, depending on the scope and the nature of the Trial, the scope of the role should be adjusted to the different activities/Trials. Having such a representative could not only ease the implementation of the necessary requirements and best practice guidelines for a Trial, but also serve as a very useful dedicated resource in the evaluation of a Trial. While the legal departments of partners in the project have been consulted during the project, e.g. for GDPR compliance, a dedicated individual with efforts to follow the actual execution of the Trials would be beneficial.

Based on the experience of **WP913** ***Research Ethics & Societal impact assessments*** the most important job in this regard takes place in advance of the Trials. However, if a new and expanded role is to be introduced in the Trial context, is seems of utmost importance to PRIO that the potential role of an ethical and/or legal expert during the execution phase of a Trial would need to be very well defined in terms of responsibilities. For example, PRIO has expertise in research ethics such as data protection issues, but are not "legal experts" that would be best suited to take responsibility for all potential emerging legal issues. In the view of PRIO, this should be someone local, with knowledge about legislation, etc. in the relevant national contexts. Furthermore, this kind of responsibility for "ethics" and "law" might even be kept as two separate roles.

Specifically, one could imagine that an "ethical expert" observes and advises on issues relating to the protection of the participants (for example relating to integrity), and a "legal expert" observes and advises on legal issues, such as national regulations, permissions, NDAs, etc. In other words, it is not a given that these two competences can be found in one person. Also, if this person is defined as an observer it would mean that she or he would not be interfering with the Trial and only reporting on what has been taking place. This is different from this role being seen as someone providing ad-hoc support, which in the understanding of PRIO would mean someone actively engaging and interfering with the Trial in case ethical issues emerge. Both of these roles have implications for the activities they are set to follow, and these implications should be carefully considered in order to mitigate potential pitfalls. In both cases, the role of such a person should also be defined in terms of follow-up, i.e. what happens with the information reported or the issues identified? Should this person for example have the authority to recommend a Trial to be stopped in a worst-case scenario where something "unethical" is unfolding during a Trial?

The partners were also asked to reflect on this issue in the ethical monitoring reports for **D913.14** ***Ethical monitoring report 4***. The feedback was mainly that this is a difficult question, and that it depends on the nature of the Trial. However, one partner reflected upon the potential role/mandate in the following way. "Before the execution of the Trial: Assure an objective and transparent solution selection process. During the Trial: Assure respect for potential and enrolled participants: privacy, commercial issues, making sure they are kept informed of new information and plans, results and lessons learned. Assuring independent, objective and careful assessment during the Trial execution and evaluation (currently covered by SP92 and SP94)". Another partner reported that "This person should take care of, *inter alia*, integrity. However, this principle should already be applied well before the execution. To ensure integrity during the execution phase, the ethics expert should work within the Trial Committee from the onset of the preparation phase, if deemed necessary. I do not see a 'new' role stepping in during execution. Moreover, such a role might not be needed."

Other partners suggest that this role could be an "ethics advisory" or "ethics support", and that such a person could take a specific role of observer focused on ethical aspects. Some partners also point out the fact that imagining the role and mandate is difficult. This remains an open issue at the time of the delivery of this report (M62).

5. Final remarks

This report is the final Ethical Monitoring Report of DRIVER+. However, the work on monitoring the project with regards to research ethics continues as part of **T913.2** ***Ethical and Societal Advisory Board***, which runs until the end of the project. Furthermore, as part of the 5th DoW amendment, **T913.1** ***Procedural ethics***, which was set to end in M62 has been prolonged until M70 and boosted with 2.5 PMs extra. In addition, the legacy of much of the work from **WP913** ***Research ethics and societal impact assessments*** continues in other parts of the project. For example, the Trial Guidance Methodology handbook will be updated in a final version in M66, and as part of this update, recommendations and issues relating to research ethics will be updated and integrated in all the checklists throughout the handbook. To complete the series of Ethical Monitoring reports, it is concluded that there have been no critical ethical issues identified within the reporting period, but that there are some issues (often recurring) that need follow-up in various ways. These issues have been documented in this report.

References

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13. **National Committee for Research Ethics in the Social Sciences and the Humanities (NESH).** *Ethical guidelines for Internet Research.* s.l. : NESH, 2014.

14. **DRIVER+ project.** *D913.21 - Minutes of the ESAB 1 & 2 .* 2018.

Annexes

Annex 1 - DRIVER+ Terminology

In order to have a common understanding within the DRIVER+ project and beyond and to ensure the use of a common language in all project deliverables and communications, a terminology is developed by making reference to main sources, such as ISO standards and UNISDR. This terminology is presented online as part of the Portfolio of Solutions and it will be continuously reviewed and updated[12]. The terminology is applied throughout the documents produced by DRIVER+. Each deliverable includes an annex as provided hereunder, which holds an extract from the comprehensive terminology containing the relevant DRIVER+ terms for this respective document.

Table A1: DRIVER+ Terminology

Terminology	Definition	Source
Data protection approval	Procedure of applying to the national or local Data Protection Authority to report about the collection, storage and/or analysis of personal data for a specific task. Whether reporting the activity is enough or actual approval is granted depends on the respective data protection authority. The task leader is generally the legal owner of this procedure.	Initial DRIVER+ definition.
Data, personal	Information relating to an identified or identifiable individual that is recorded in any form, including electronically or on paper.	ISO/IEC TR 24714-1:2008(en) Information technology — Biometrics — Jurisdictional and societal considerations for commercial applications — Part 1: General guidance, 2.9.
Data, sensitive	Data with potentially harmful effects in the event of disclosure or misuse.	ISO 5127:2017(en) Information and documentation — Foundation and vocabulary. Link: https://www.iso.org/obp/ui/#iso:std:iso:5127:ed-2:v1:en:term:3.1.10.16
Experiment	Purposive investigation of a system through selective adjustment of controllable conditions and allocation of resources. DRIVER+ note 1: Please consider also the notes in the original definition. DRIVER+ note 2: In the context of DRIVER+ Trials are executed – and not experiments.	ISO/TR 13195:2015(en) Selected illustrations of response surface method — Central composite design. Link:https://www.iso.org/obp/ui/#iso:std:iso:tr:13195:ed-1:v1:en
Lessons Learned	Lessons learning: process of distributing the problem information to the whole project and organization as well as other related projects and organizations, warning if similar failure modes or mechanism issues exist and taking preventive actions.	ISO 18238:2015(en) Space systems — Closed loop problem solving management, 3.3.

[12] The Portfolio of Solutions and the terminology of the DRIVER+ project are accessible on the DRIVER+ public website (https://www.driver-project.eu/). Further information can be received by contacting coordination@projectdriver.eu.

Terminology	Definition	Source
Observer	Observer participant who witnesses the exercise while remaining separate from exercise activities. Note 1 to entry: Observers may be part of the evaluation process.	ISO 22300:2018(en) Security and resilience — Vocabulary. Link: https://www.iso.org/obp/ui/#iso:std:iso:22300:ed-2:v1:en:term:3.154
Research ethics	The ethics of the planning, conduct, and reporting of research; this pertains in particular to rules and guidelines for the participation and protection of individuals taking part in the research activities.	Initial DRIVER+ definition.
Trial	An event for systematically assessing solutions for current and emerging needs in such a way that practitioners can do this following a pragmatic and systematic approach.	Initial DRIVER+ definition.
Trial Guidance Methodology (TGM)	A structured approach from designing a Trial to evaluating the outcomes and identifying lessons learned.	Initial DRIVER+ definition.
Volunteer	[SV [spontaneous volunteer] Individual who is not affiliated with an existing incident response organization or voluntary organization but who, without extensive preplanning, offers support to the response to, and recovery from, an incident]	ISO 22319:2017(en) Security and resilience — Community resilience — Guidelines for planning the involvement of spontaneous volunteers, 3.1. Link: https://www.iso.org/obp/ui/#iso:std:iso:22319:ed-1:v1:en:term:3.1

Annex 2 - Ethical Monitoring Questionnaire for D913.1 *Ethical Monitoring Report 4*

Ethical Monitoring Questionnaire, for D913.14

PRIO is currently preparing the final Ethical Monitoring Report of the project, and as for the previous three reports, we ask the project partners for input with regards to what kind of ethical issues they have encountered or are expecting.

Please reply to the questions below as detailed as you can, and return the questionnaire to PRIO by 29th May at the latest. The information collected will be used for the purposes of D913.14 only, and will not be shared with outside parties without permission. Any potential personal information will be kept confidential. The final Ethical Monitoring Report will be submitted in M62, and it will serve as the basis for the final meeting between PRIO and the Ethical and Societal Advisory Board. Please contact PRIO (stiber@prio.org) for any questions.

Name/ partner organization:

Which SP and/or WP are you answering on behalf of?

General questions

1. Within the scope of the activities of the SP/ WP, have you been in contact with local ethics committees or Data Protection Authorities?
   a) If yes: please describe shortly the process. E.g. did any of the WP's encounter (unforeseen) problems or challenges (e.g. lack of answer, unclear guidelines, or unclear responsibilities)?

   b) If no: do you foresee that such contact will be necessary for future activities? And do you expect any problems or challenges in relation to data protection requirements or research ethics?

2. Has the template for "Application for Research Ethics Approval", prepared by PRIO, been used for activities within your SP/ WP? Yes or no?
   a) Are you aware of any plans to use it in the future?

3. Has the template for obtaining "Informed consent", prepared by PRIO, been used for activities within your SP/WP? Yes or no?
    a) Are you aware of any plans to use it in the future?

    b) Have you dealt with informed consent issues in the project since June 2018? And if so, did you use another template?

4. In which way are the new EU General Data Protection Regulation (GDPR) requirements reflected upon in your institution's DRIVER+ activities? Are you aware of any challenges partners within the SP/ WP have with regards to adhering to the new requirements?

5. Have any issues relating to data protection or research ethics come up for the work within the scope of this SP/ WP in DRIVER+ that you have not experienced before? Is there anything distinctive about DRIVER+? If yes, please provide a brief explanation.

6. In the scope of the project activities, are there still challenges in your work that has to do with research ethics? If yes, describe these briefly.

7. Looking back on the project as a whole, what has changed since the beginning of the project? Did you learn something new regarding research ethics? What has been the main challenges?

8. If we imagine that an "ethics expert" were to be present also during the execution phase of a Trial, what kind of role/ mandate do you think this person should ideally have?

9. As part of the activities in your SP/ WP, have any emerging issues relating to research ethics been identified since the last ethical monitoring report (M50- June 2018)? If so, how are they being tackled?

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

11. Do you have any other comments?