D95.21- Planning for the Ethical Approvals

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Administration, Research ethics, process monitoring plan, data protection approval, Special Clause 15, planning for Ethical Approvals

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<td>D</td>
<td>Deliverable</td>
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<td>DoW</td>
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<td>DPA</td>
<td>Data Protection Authority</td>
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<td>EC</td>
<td>European Commission</td>
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<td>ESAB</td>
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<td>General Data Protection Reform</td>
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<td>REA</td>
<td>Research Executive Agency</td>
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<td>SC15</td>
<td>Special Clause 15 of the grant agreement with the European Commission</td>
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<td>SP</td>
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<td>UAV</td>
<td>Unmanned Aerial Vehicle</td>
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<td>WP</td>
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Project Description

DRIVER evaluates emerging 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 emerging solutions for professional responders with a focus on improving the coordination of the response effort.
- Benefiting professionals across borders by sharing learning solutions, lessons learnt 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

Research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. For research carried out in European projects these standards are derived from the European Convention of Human Rights, the European Charter of Fundamental Rights and the Treaty of the European Union in general, in addition to a range of relevant directives, communications, and executive orders, in particular the European Directive 95/46/EC39 for the protection of personal data. These obligations are not merely ethical in nature, they are contractual. They are embedded in the Grant Agreement of the DRIVER project in a variety of ways, most prominently through the general contractual mechanism put in place in order to assure this high standard of research ethics, known as Special Clause 15. SC15 applies to all forms of research, experimentation, testing and demonstration. Research conducted within DRIVER is subject to SC15. This deliverable describes the plan for how PRIO will monitor the partners’ obligations to fulfil the requirements for maintaining this high standard.

It is important to distinguish between the planning for the monitoring of ethical approvals (this deliverable) and the detailed guidelines for research ethics and principles (Old: D91.3). This deliverable is a resubmission of D95.21, and sets out a plan for monitoring the former. It contains both the key principles of SC15 and explains which legal consequences are connected to such approvals. It explains the DRIVER strategy to efficiently monitor the process of getting these approvals and introduces the different questions that need to be answered by each institution conducting research in order to judge whether their research is subject to SC15. It also prepares and sensitizes the consortium towards research ethics altogether, the relevant principles and procedures of which is delivered in D91.3.

This deliverable provides also a questionnaire about data protection that can help to perform the first step in assuring that the research carried out is in conformity with SC15 of the DRIVER Grant Agreement. This questionnaire will help to assess whether the research conducted in the different tasks will need ethical approval. The heart of the deliverable is a table, indicating the approvals needed as per DRIVER task (updated December 2015) as well as an introduction on how to apply for approval at the relevant local authority, such as Data Protection Authorities or other ethical authorities or committees (c.f. D91.3 for more details).
1 Introduction

This administrative deliverable has as its primary aim to describe how PRIO will ensure that every partner in DRIVER obtains the required and relevant research ethics approvals for every activity in the project.

This overview visualizes how this deliverable fits into the overall research ethics in DRIVER:

While this visualization shows all the different components in the work relating to research ethics in DRIVER, all the different components are in one way or another feeding in to each other. This is briefly described below:

1. Planning for Ethical Approvals
   a. This current deliverable is the first document submitted on research ethics in the project, and it has two functions: to describe how the process of making sure that every partner obtains the relevant approvals for their activities, and to describe some basic guidelines for how this obtaining should happen.

2. Collecting the Ethical Approvals
   a. In this task and in these deliverables, the actual collecting of the packages of approvals and notifications to the relevant Data Protection Authorities or other ethics bodies, are collected from every partner by PRIO, gathered in a table with all
the relevant documentation attached, before everything is submitted to REA. This happens annually, but the work of following up with every partner, is continuously taking place throughout the year.

3. Guidelines for Research Ethics
   a. This deliverable (D91.3), which was accepted in Year 2, contains the full and detailed guidelines for research ethics. This includes step-by-step guidance for how to decide if an activity is subject to approval, what kind of approval this might be, and it also contains more detailed information of the importance of research ethics altogether as well as checklists and other practical supporting material.

4. Ethical Monitoring Reports
   a. The annual Ethical Monitoring Reports document and address key research ethical issues in each year of DRIVER, and 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 PRIO and as experienced by the DRIVER consortium. The latter information is derived from Ethical Monitoring Questionnaires sent out to 25 of the project partners as per DoW. In addition, these reports also reflect the insights and issues from the annual DRIVER Ethical and Societal Advisory Board (ESAB) meetings. In this way, the most relevant information is consolidated in this report that serves as an update on the totality of the work on research ethics in DRIVER.

5. Ethical and Societal Advisory Board (ESAB)
   a. The ESAB will meet six times throughout the project. In the meetings, led by PRIO, the Board discusses the most important, challenging and crucial issues relating to research ethics in the project for the current period. This can be practical challenges relating to ethical approvals, or more fundamental issues that might need to be tackled. So far, the Board has provided useful advice to the project e.g. both with regards to data protection dilemmas in relation to data collection across borders, and they have provided their feedback and input on the design and the different components of the Societal Impact Assessment Framework, which is part of the methodology for the DRIVER experiments. The minutes of these meetings are submitted as deliverables.

Research conducted within DRIVER is subject to Special Clause 15. The aim of this deliverable is to set out a plan for the monitoring of getting the relevant approvals. It describes both the key principles of SC15 and explains which legal consequences are connected to such approvals. However, the key purpose of the deliverable is to explain the DRIVER strategy to efficiently monitor the process of getting these approvals and introduces the different questions that need to be answered by each institution conducting research in order to judge whether their research is subject to SC15. It also prepares and sensitizes the consortium towards research ethics altogether, the relevant principles,
guidelines and procedures of which is explained in D91.3. Since the information process about research ethics had to start early in the project, and D91.3 was only due already in October 2014, this deliverable contains some parts of D91.3, since some basic instructions for how to obtain the relevant approvals and what might trigger them, was needed already from the very beginning of DRIVER. However, the detailed guidelines for research ethics and principles can be found in D91.3, which is the main deliverable for getting guidance and recommendations for research ethics in DRIVER.

In the following, the practical implementation of these guidelines and recommendations are described.

1.1 Structure of the deliverable

The setup for this deliverable is as follows. Chapter 2 describes the general setup for planning for the ethical approvals. It describes shortly the two potential types of ethical approvals that might be needed in DRIVER, since this is needed for identifying and monitoring the different research activities in DRIVER. Then, the process of informing the consortium about the relevant procedures, and the relation between this deliverable and D91.3 “Ethical procedures, risks and safeguards” is described. Chapter 3 is a guide to SC15, and introduces the basic principles and practical implications of this obligation. Chapter 4 describes the legal consequences of not adhering to the general rules for research ethics, as well as some potential pitfalls in terms of ethics. Chapter 5 introduces the key aspects of the new General Data Protection Reform of the EU. Chapter 6 is the core of this deliverable, and contains the overview of ethical approvals needed from Data Protection Authorities per WP/Task for the duration of DRIVER. Chapter 7 lists the 10 DRIVER rules for data protection and informed consent. Chapter 8 describes how to concretely go about in order to obtain the relevant approvals. Chapter 9 foresees what kind of approvals might be needed for the DRIVER experiments, and how ethics considerations are integrated into these, although the experiments are still under planning. It also includes a short questionnaire about data protection, to be used by the partners. Finally, chapter 10 concludes and describes how WP130 supports the project in terms of research ethics. In annex, a letter exemplifying the information process from PRI to the DRIVER consortium is attached.
2 Planning for Ethical Approvals

2.1 The importance of ethics in research

Ethical tensions are part of the everyday practice of doing research—all kinds of research in all kinds of areas. The obligation to respect research ethics is part of the responsibility for research in general, and both project managers, individual researchers, research institutions and various authorities share the responsibility for ensuring sound ethics in research [3: 5]. Research ethics is not only a matter of legal and contractual obligations, but it is also a larger question of societal impact, accountability, and individual and institutional moral. Research ethics, as such, refer to a complex set of values, standards and institutional schemes, that are meant to constitute and regulate scientific activity [3: 5]. The research ethics guidelines, which can be found in D91.3, are a practical tool for the researchers in DRIVER. These guidelines describe in detail the different factors which researchers should take into account in the various parts of their research activity. While adhering to these are of crucial importance for the success and sustainability of DRIVER and its outputs, the authors of this deliverable neither assume or possess any judicial function in case of breaches of these standards, and cannot impose any sanctions on project partners who might not fulfil this obligation.

2.2 Difference in research type and approvals needed

There are two types of research carried out in DRIVER that are regulated by Special Clause 15: interviews and experiments. Both types may involve the collection and processing of data about humans, which are subject to approval by the data protection authorities (DPAs) of the country in which the data is collected, and potentially also of those countries in which the data is processed, should that be a different country. Experiments, however, might require additional authorizations from other national ethics authorities, if certain requirements are fulfilled.

While the detailed planning of the DRIVER experiments is still ongoing, both with respect to methodologies and points in time, the planning for the interview activities within the DRIVER project are already more concrete. As a result, in the beginning of the project, the PMC decided to initiate a two-stage monitoring procedure to get an overview of the research conducted in the DRIVER project: a first initiative is directed to identify research tasks and work packages involving the collection and processing of data through interviews conducted within DRIVER in order to coordinate the approval processes at the different data protection authorities.

1 Such as the exchange or collection of sensitive personal data, the involvement of vulnerable groups, or if the experiments have a significant effect on the public.
However, while the planning and restructuring of the project is currently ongoing as this deliverable is submitted, the annual Ethical Monitoring Reports will nonetheless capture any changes in requirements and attention that might emerge in the context of research ethics. In these reports, the responsible partner (PRIO) also has the opportunity to present updated advice and guidelines, for example relating to the new General Data Protection Reform by the EU (see chapter 4), or related to the potential need for less common kinds of approvals from other national ethics committees.

### 2.3 Process of informing the consortium

The first step in ensuring that research ethics in DRIVER is properly regulated, is to provide all project partners with information about procedures and guidelines. This work started already in the very first month of DRIVER, and in T95.2. In order to inform the DRIVER consortium and to identify where and when in the DRIVER project research is conducted, that falls under the regulation of Special Clause 15, the very first step taken by PRIO was to distribute to all subproject leaders some basic information in the second month of the project. This email:

- stated the importance of compliance with Special Clause 15,
- explained the key principles of Special Clause 15 in a specific documents (cf. point 3),
- formulated 2 questions that work package (WP) and task leaders need to answer in order to judge whether their research may need approval from data protection authorities (cf. point 4.)

This was the first step in informing the project partners about the requirements and the necessary steps to take. Within this mail, subproject (SP) leaders were concretely asked to contact WP leaders of the respective subproject who had two weeks to answer the two questions about their tasks. Key tasks and foreseen scheduling of such tasks was reported back to leaders of the former SP9, which held the responsibility for this task.

This approach was not only chosen to ensure efficient feedback, but for three additional reasons. Firstly, because only WP and task leaders are in the position to judge what kind of research they will be conducting within the scope of their task, meaning exactly where and when such research activities will take place and what kind of data and methodologies this research involves. Secondly, because subproject 9 (after first restructuring: WP130) of the DRIVER project foresees a participatory and didactic approach to research ethics that includes the active involvement of all researchers who will conduct research within DRIVER. Thirdly, because only those who will legally own the data (meaning collecting and processing it) can apply for approval.

The information gathered from all the SP leaders was integrated into an overview chart in order to facilitate and plan for the monitoring process. According to this chart, each partner is contacted by

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2 The general progress of this task is detailed in *D11.51 Formal Year 1 Period Report*, and in *D95.31 Ethical Monitoring Report 1*. 

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PRIO four months before the research is supposed to be conducted. The partner will receive the DRIVER guidelines *Getting ethical approval* (submitted as part of the accepted D91.3) that explains in a simple way how to apply for approval, meaning that those who will select participants, generate or obtain the data, will be required to apply to obtain approval for each distinct research, experiment, testing or demonstration activity from the ethics review board most local for the responsible research partner (who is also likely to be the partner who generates, processes, stores, deletes the data). This guide is developed in parallel and is part of D91.3. If research is geographically conducted in several places, meaning that personal data is collected from several countries and jurisdictions in the same process, several authorizations may need to be obtained. This authorization, once obtained in written form, will be submitted to the REA prior to the commencement of the relevant research.

In sum, early in the project, all SP leaders were contacted and informed about the potential need for ethical approvals, and the possibilities for merging approvals when this was appropriate was discussed. The very first version of D95.21 “Planning for the Ethical Approvals” did not only foresee a planning of monitoring activities from PRIO’s side, but it included concrete steps, forms and information packages for all task leaders, which clarified the role of ethical approvals and how to obtain them. The deliverable was distributed already in M2 of the project. The monitoring of ethical approvals was then further detailed in D95.22, which was submitted in M6. The importance of ethical approvals (including data protection) has been continuously emphasized regularly by mail and during PMC meetings and bilateral communications, at the GA in Ispra and by the Project Officer at the first ESAB meeting in M8.

Based on the setup for monitoring the ethical approvals as described in this deliverable, two rounds of approvals have already been collected and sent to the REA. These are D95.22 (submitted in M6, accepted) and D95.23 (submitted in M18, rejected, resubmitted Y2). In relation to the submission of these two collected packages of approvals (which are in a sense the concrete output of the planning process described in this deliverable), all DRIVER partners were reminded at several occasions of the relevant procedures for obtaining ethical approvals (this information process is described in Chapter 2.2 of D95.22 and in Chapter 2.2 of D95.23).

### 2.4 Relation to D91.3

The original version of D95.21 was reviewed by a member of the DRIVER Ethical and Societal Advisory Board, but it was also written with a strong relation to D91.3. D91.3, which was accepted in Year 2, introduces the concept of research ethics in detail and explains why ethical considerations are crucial in DRIVER, but most importantly it sets out the basic guidelines to be followed in order to uphold the high ethical standards required for the project. The deliverable fulfils two purposes: 1) it provides a basic introduction to research ethics that covers all the main aspects and areas, and 2) it discusses and addresses in more detail, some particular issues that are relevant for ensuring that DRIVER is conducted while adhering to the highest ethical standards. Because the original submission of D95.21 was due before the original version of D91.3, a basic introduction regarding how to obtain
data protection approval was included already in D95.21 although the main deliverable for giving such guidance is D91.3.

While this chapter has described the general setup for planning for the ethical approvals in DRIVER, the next chapter contains a practical guide to SC15 and introduces the basic principles and practical implications of this obligation.
3 Guide to Special Clause 15

3.1 Basic principles

Research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. For research carried out in European projects these standards are derived from the European Convention of Human Rights, the European Charter of Fundamental Rights and the Treaty of the European Union in general, in addition to a range of relevant directives, communications, and executive orders, in particular the European Directive 95/46/EC39 for the protection of personal data. These obligations are not merely ethical in nature, they are contractual. They are imbedded in the Grant Agreement of the DRIVER project in a variety of ways, most prominently through the general contractual mechanism put in place in order to assure this high standard of research ethics, known as Special Clause 15.

3.2 Special Clause 15

All research activities carried out as part of the DRIVER project are subject to Special Clause 15 of the grant agreement with the European Commission. This means, in a nutshell, that all research activities must obtain approval from an appropriate research ethical review board before the research is carried out. This is done by applying directly to the most local ethical review board. An application for ethical review contains a detailed description of the exercise envisaged, including information about who is involved, what is to be done, where, when and how. It should provide detailed description of provisions to be taken to project the safety and well-being of both researchers and the objects of the research exercise.

Special Clause 15 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.

3.3 Practical implications of Special Clause 15 for the DRIVER project

Special Clause 15 applies to all forms of research, experiments, testing and demonstration.
Researchers shall work on the basis of basic respect for human dignity [3: 11]. This means that wherever human beings are involved in research activities, measures are to be taken to ensure their safety and wellbeing. This applies to the researchers carrying out the research, to those individuals who might be indirectly impacted by the research, and to those human beings that might be objects of the research through direct study, indirect observation, interviews, data collection or other means. It also refers to the secondary impacts of the research, experimentation, testing and demonstration upon uninvolved bystanders, the environment, economic conditions, and human development in general, etc.

For the DRIVER project, Special Clause 15 will thus have 3 primary areas of application:
1) The safety, well-being, and rights of researchers;
2) The safety, well-being, and rights of bystanders;
3) The safety, well-being, and rights of objects of research

Similarly, the Norwegian National Ethics Committee, summarizes the obligation to respect human dignity by highlighting three certain standards that the research process must uphold [3: 11]:
- Ensuring freedom and self-determination
- Safeguard against harm and unreasonable suffering
- Protecting privacy and close relationships

As part of a guide for designing educational setups for teaching research ethics, one of the members of the DRIVER Ethical and Societal Advisory Board, has published a brief summary of the most crucial issues and concerns, which every researcher doing research that involves humans, should be aware of and take into account. The three particularly crucial issues are informed consent, confidentiality and protection of privacy [4]. All three of the ethical risk areas fundamentally also engage the principle of informed consent. Whether involved in the research as a researcher, a bystander or an object of research, individuals have the right to be informed and fully understand the research in which they are involved. Their consent to participate based on full information must be documented, where appropriate, via the collection of individual statements of informed consent.

All three of the areas of application mentioned above engage the Special Clause 15 requirement of seeking approval for each research, experiment, testing or demonstration activity from the relevant local research ethics review board. This includes safeguarding the privacy of the participants. However, to what extent future DRIVER experiments are affected by SC15 is subject to further analysis after the respective activities have been planned in detail. This means, for example, that the well-being of either researchers, bystanders or others will most likely not be put at any risk.

The third category of ethical issues—the safety, well-being and rights of human objects of research—is in general more complex and labour-intensive since it requires that the rights of human objects of research relative to their own personal data is respected. As part of the application for approval from the local research ethics review board, this type of research activity requires
specification of how personal data is to be collected, transferred, and stored, and procedures for anonymity, where appropriate. The part of the ethics management concerning personal data also requires its own informed consent declaration, confirming that the individual from whom personal data is being collected understands all the relevant details of the research, experimentation, or demonstration activities and consents to participation based on this information.

3.4 Obligations as a researcher under Special Clause 15

In summary, in order to correctly conform to the DRIVER project’s contractual obligations under Special Clause 15 all research, testing and demonstration activities should be carefully designed, specified in detail, including all relevant provisions, safeguards, information about the background, aims, procedures, place, time and participants in each particular exercise and, where relevant, specific plans for collecting documentation of the informed consent to participation of all individuals involved.

Most universities and large research institutes will have their own internal ethics review board. In other cases, the county, regional or municipal board will be the appropriate one. The principle to be applied is that the local, lowest-level board should be addressed. In the absence of other alternatives the national ethical review board should be addressed.

3.5 Special challenges for data collection under Special Clause 15

The most common type of ethical challenge for the DRIVER project will be associated with the collection of information from or about human subjects. As mentioned above, in general, two main issues are involved when collecting data from or about human subjects: informed consent and data protection. Both of these are highlighted as particularly relevant in several sources on research ethics [3] [4].

3.5.1 Informed consent

Human participants in research exercises, who either actively or passively provide information, have a right to be fully informed about the research in which they are involved. They must provide consent in writing that they have been informed. The most common way to assure this is through an information sheet about the DRIVER project, including all details about the project, including funding, participants, aims, assumptions, etc. The information sheet should describe the specifics of the planned research and how the data collected will be handled. The same sheet should be signed by all participants.

Before taking part in any research, participants have the right to be informed:
• That participation is voluntary;
• That they may ask questions and receive understandable answers before making a decision about participation;
• The degree of risk and burden involved in participation;
• Who will benefit from participation;
• That they may withdraw themselves and their data from the project at any time;
• How their data will be collected, protected during the project and destroyed at the end.

3.5.2 Data protection

Research carried out under Special Clause 15 invokes several obligations with regard to sharing and/or archiving confidential research data, since much research data about people—even sensitive data—can be shared ethically and legally if researchers employ strategies of informed consent, anonymization and controlling access to data. These are the key obligations in terms of handling data:

• To assure confidentiality towards informants and participants;
• To protect participants from violation by not safeguarding sensitive information;
• To recognise that participants have propriety over their personal data and are able to make their own decisions on how the information they provide shall be used, shared and made public (through informed consent);
• To inform participants about how information and data obtained will be used, processed, shared, and disposed of.

In the next chapter, the legal consequences of not adhering to the general rules for research ethics (as described in the current chapter), as well as some potential pitfalls in terms of ethics, are described.
4 Legal consequences & potential ethical pitfalls

4.1 Legal consequences

Compliance with ethical principles and data protection regulations is a legal requirement. Breaches may result in investigations, significant fines, adverse publicity and civil or criminal liability. Although the consideration of research ethics and data protection law may seem like an additional burden, much of it is plain common sense and, indeed consistent with the requirements of high quality research. It is the partner leading the task including data collection that carries the legal responsibility for having the appropriate approvals and notifications in place. While PRIO provides guidelines and recommendations, PRIO is not legally responsible for ethical approvals that the activities might need.

4.2 Credibility in research ethics

‘Credibility’ refers to the quality of being trusted and believed in, or the quality of being convincing or believable. It could also refer to the quality or power of inspiring belief, or the capacity for belief. The researcher holds the responsibility for ensuring the credibility of the research. While the practical implementation of the concept of research ethics will vary between different sectors and industries, this section of the deliverable will list some key “cardinal sins” of research conduct, as these represent particular threats for the credibility of the research. A breach in any of these three areas will undermine the integrity of the research, potentially both for the individual researcher, the organization, the university or the research field as such.

4.2.1 Fabrication

‘Fabrication’ commonly refers to the action or process of manufacturing or inventing something, it can also refer to an invention, as in a lie. In the context of research ethics, the concept would refer to the intentional misrepresentation or research results, e.g. by making up data. Attempts to systematically measure the frequency of such misconduct show that up to 33.7% of surveyed researchers admitted questionable research practices; likely a conservative estimate. The intent to deceive the audience or the scientific community, makes fabrication one of the “cardinal sins” in research. There is little doubt about the fraudulent nature of fabrication, and that it is a form of

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5 Summarized by e.g. PennState University. https://www.education.psu.edu/bioet533/node/654
scientific misconduct. Different definitions are adopted by different institutions, but they all agree that fabrication (invention of data or cases) is a serious form of misconduct [6] [7].

The involvement of crisis management professionals in DRIVER, already ensures a sensibility towards the guidelines and rules for fabrication. However, the concrete guidelines for DRIVER research ethics provided in D91.3, specifically underscore the importance of ensuring just and correct data collection, data processing and data sharing. By following these guidelines, the risk of fabrication is already minimized.

4.2.2 Plagiarism

The issue of plagiarism is an important part of research ethics. Plagiarism often refers to borrowing or copying someone else’s original ideas, but some argue that the use of terms like “copying” and “borrowing” in fact can disguise the seriousness of the offense7.

*Plagiarism is, perhaps, the most common form of research misconduct. Researchers must be aware to cite all sources and take careful notes. Using or representing the work of others as your own work constitutes plagiarism, even if committed unintentionally. When reviewing privileged information, such as when reviewing grants to journal article manuscripts for peer review, researchers must recognize that what they are reading cannot be used for their own purposes because it cannot be cited until the work is published or publicly available.*8

Some scholars argue that plagiarism cannot be cast as a simple black-and-white-issue, but must be understood in terms of complex relationships between text, memory and learning [9]. In other words, plagiarism can mean several things, and is not only about copying a section of text without giving proper credit to the source. However, plagiarism can rather easily be avoided by making sure to always cite the source the information is derived from, correctly. As a general rule, it is better to cite too much than too little. For further instructions on how to concretely collect and handle data in the best way, see the detailed guidelines in D91.3.

4.2.3 Falsification

Falsification refers to a form of scientific misconduct that basically means that research data or evidence is falsified. Although the frequency with which scientists falsify data or evidence is subject to controversy, some academic contributions (a meta-analysis of several surveys9) suggest that the frequency might be higher than what one would assume.

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7 http://www.plagiarism.org/plagiarism-101/what-is-plagiarism
8 https://www.e-education.psu.edu/bioet533/node/654
Falsification is the changing or omission of research results (data) to support claims, hypotheses, other data, etc. Falsification can include the manipulation of research instrumentation, materials, or processes. Manipulation of images or representations in a manner that distorts the data or “reads too much between the lines” can also be considered falsification\(^\text{10}\).

Deliberate falsification is closely related to fabrication (cf. chapter 3.7.1). In DRIVER, the guidelines for research ethics delivered in D91.3, gives advice for how to avoid making the common mistakes that might lead to scientific misconduct. In the case of falsification, the existence of the research ethics guidelines and a common methodology for conducting the DRIVER experiments, will advise and steer the scientific activities in the project.

This chapter has described some legal consequences of not adhering to the general rules for research ethics, as well as some potential pitfalls in terms of ethics. Moving on, the next chapter introduces the key aspects of the new General Data Protection Reform of the EU, a reform that is likely to have an impact in the way obligations relating to data protection and privacy is organized.

\(^{10}\) https://www.e-education.psu.edu/bioet533/node/654
5 The New General Data Protection Regulations (GDPR) of the EU

The following chapter is about the EU Data Protection Reform, which was initiated in 2012, and which will come into effect in the spring of 2018. While it is not yet clear how concretely this reform will have a direct impact in the research in DRIVER, some general information is provided in this deliverable, to sensitize the project partners towards this approaching change, and to already give some indications of what kind of changes the reform is likely to entail. At the minimum, it can already be made clear in which general areas the reform will have the most significant impact on research.

According to the European Commission, the regulation is an essential step to strengthen citizens' fundamental rights in the digital age. The reform was put forth in January 2012, and on 15th December 2015, the European Parliament, the Council and the Commission reached an agreement on the new data protection rules, establishing what is described as a modern and harmonised data protection framework across the EU. The reform will have an impact on research «by harmonizing privacy legislation across the EU member states and carving out exemptions for scientific, historical and health research », and thus the « GDPR seeks to reconcile the often competing values of privacy and innovation ».

While the Regulation has formally entered into force on 24th May 2016, it shall apply from 25th May 2018. The Directive entered into force on 5th May 2016 and the Member States are obliged to transpose it into their national laws by 6th May 2018 [5].

An article by De Hert and Papakonstantinou sets out to assess the new Regulation’s ability to protect individuals, comparing and contrasting it with the provisions as set out in the Directive. Nearly all individuals will now be affected by the Regulation in some way or another, and the circumstances in which the 1995 Directive was originally drafted have all changed. The argument of harmonizing the data protection approach among the Member States was crucial in

14 The European Parliament’s Civil Liberties committee and the Permanent Representatives Committee (Coreper) of the Council then approved the agreements with large majorities. The agreements were also welcomed by the European Council of 17th -18th December as a major step forward in the implementation of the Digital Single Market Strategy. On 8th April 2016 the European Council adopted the Regulation and the Directive, and on 14th April 2016 the Regulation and the Directive were adopted also by the European Parliament. On 4th May 2016, the official texts of both the Regulation and the Directive were published in all official languages, in the EU Official Journal.
the call for an update of the Directive, and data protection is now considered an EU concern to be regulated directly at EU level through a Regulation [5].

As has implications for research, the distinction between « personal data » and « sensitive personal data », the distinction between an identified and identifiable natural person has been upheld in the Regulation. The Regulation includes a general prohibition for the processing of sensitive data. In terms of planning for and carrying out the procedure for ensuring fair data processing etc., it can be noted that the personal data processing actors, the already existent system of data subjects, data controllers, data processors, recipients and third parties has been more or less maintained in the new Regulation text (although this is seen by the authors of [5] to be a somewhat static approach).

In terms of the Directive’s key principles, The Regulation provides a new list of personal data protection principles:

- lawfulness,
- fairness and transparency,
- purpose limitation,
- data minimisation,
- accuracy,
- storage limitation,
- integrity and confidentiality,
- accountability.

The lawful grounds for so called « processing operations » continue to be six [5]:

- consent,
- performance of a contract,
- compliance with a legal obligation,
- protection of vital interests,
- public interest,
- overriding interest of the controller.

Although the Commission´s request for «explicit» consent has not been included in the final draft of the reform, informed consent still remains one of the most important issues for research ethics and data protection and privacy issues. Individual consent is described in the following way : « Any freely given, specific, informed and unambiguous indication of his or her wishes by which the data subject, either by a statement or by a clear, affirmative action, signifies agreement to personal data relating to them being processed.».

Another much debated issue in the new reform is the so called « right to be forgotten », which can be found in Article 17 of the Regulation. This article, in general terms, sets out the individual’s right to have their personal information deleted by data controllers. The right to data portability, is also a
new right in the Regulation, stating that individuals are free to move around their personal data from controller to controller, e.g. if an individual changes phone operator to a new one.

It is also important to note that the DPAs, the Data Protection Authorities around Europe, have had their roles further strengthened as a result of the reform. Efforts have been made to enhance cooperation and a coherent approach to data protection and privacy across Europe. «Lead DPA» has been introduced as new basic notion. From a research perspective, it is furthermore important to note that the general obligation to notify the DPAs about any personal data processing operations, seems to have shifted to a principle of accountability [5].

Later, other ethics deliverables in DRIVER, such as the annual Ethical Monitoring Reports, will deal with practical implications and consequences of the reform, in more detail.

Having described some of the key aspects of the new General Data Protection Reform of the EU, the next chapter is considered the main chapter of this deliverable, as it contains the overview of approvals needed by Data Protection Authorities per WP/Task.
6 Overview of Approvals needed by Data Protection Authorities per WP/Task

The table below indicates the approvals needed as per DRIVER task. All subproject leaders have been asked to flag those tasks that can include the collection and processing of data about humans. PRIO has verified this information in the DoW.

The table presented in the following indicates in particular:

- a) for which task research data about humans is collected,
- b) when approximately the activity will take place and when partners should start applying for the approval,
- c) who is responsible for the activity,
- d) what kind of method is used to collect or gather data,
- e) whether an approval has been applied for or not.

The table will serve as a follow-up tool to monitor whether and when applications for approvals are being written. PRIO will contact the most urgent cases directly. The table will be continue to be updated every 12 Months to ensure that potential changes in the schedule or the DoW are accounted for.\textsuperscript{16}

All DRIVER partners are asked to pay attention to the following:

1. All partners need to make sure that they follow the table’s schedule to apply for ethical approval at their local Data Protection Authority. We thus ask the responsible partners to identify their local data protection authority as soon as possible.
   a. The table suggests starting the approval process on average 4 months before the research is meant to begin.
   b. Without approval, data collection should not start.
   c. Approval needs to be applied for by the principal researcher of the research done, who takes full legal responsibility for the collection and potential storage of data.
   d. The approval needs to be applied for at the local data protection authority of where the principal researcher’s institute is situated.

2. Partners need to keep in mind that there are tasks and activities which may collect, gather or store data about humans for their own work package, but also produce data that will be re-used in other tasks later on in the project. The planned or foreseen use of data will have to be specifically mentioned in the applications.

\textsuperscript{16} As soon as the final structure of the revised DRIVER is approved, this table will be updated thoroughly again.
3. Some work packages include **different principal researchers**, combine **different kinds of methods** and **different kinds of data** (e.g. a collection of personal data via an UAV is very different from a questionnaire sent to an End-user). Should the principal researchers, methods and kinds of data vary separate approvals will have to be applied for.
   a. However, to make approval work more efficient each principal researcher is asked to check their tasks and activities for **possibilities to combine the approval process wherever possible and sensible**.
   b. PRIO can be consulted for advice.

**Example:**

```
If a Dutch partner conducts workshops with participants from Italy, Spain and Poland in Belgium, the Dutch researcher will have to identify its local data protection authority in the Netherlands and apply for approval there – not in Belgium or in the countries of the workshop participants. If the Dutch partner repeats the same or a similar workshop later on in the project, they should try to integrate this second workshop in the first approval application. If the same workshop is being repeated later by a French partner, the French partner will have to apply at their local data protection authority, too. Never combine applications that have different principal researchers.
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The next chapter is the core of this deliverable, and contains the overview of ethical approvals needed from Data Protection Authorities per WP/Task for the duration of DRIVER.
<table>
<thead>
<tr>
<th>Task</th>
<th>New Task/ Changes</th>
<th>Lead Partner</th>
<th>Start activity</th>
<th>Application (M)</th>
<th>Mention in DoW</th>
<th>Application sent</th>
<th>Approval received</th>
<th>Comments (status before/ after restructuring)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T32.2</td>
<td>T32.2</td>
<td>DRC</td>
<td>M4-M24</td>
<td>M4, activity postponed</td>
<td>Have sent application and received answer that no approval is needed, also parts that take place in Israel don't need approval</td>
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<tr>
<td>T32.3</td>
<td>T32.3</td>
<td>DRC</td>
<td>M4-M24</td>
<td>M4, activity postponed</td>
<td>Have sent application and received answer that no approval is needed, also parts that take place in Israel don't need approval</td>
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<tr>
<td>T36.2</td>
<td>T36.2</td>
<td>FRQ</td>
<td>M1-M36</td>
<td>6</td>
<td>German DPA only give generalized approvals. WP leader has been in contact with PRIO, but final notification (of USTUTT to DPA + reply) still needs to be sent to PRIO. 01/10/2015: Willi Wendt will update us on the procedure from USTUTT.</td>
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<tr>
<td>T36.2</td>
<td>T36.2</td>
<td>AIT</td>
<td>M1-M36</td>
<td>7</td>
<td>German DPA only give generalized approvals. WP leader has been in contact with PRIO, but final notification (of USTUTT to DPA + reply) still needs to be sent to PRIO. 01/10/2015: Willi Wendt will update us on the procedure from USTUTT. Patrick Drews will send updates, potentially there will be changes due to reorganization. Dreas will get back to Marseille. Willi Wendt asked to update table and documentations and conduct review.</td>
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<tr>
<td>T24.3</td>
<td>T24.1</td>
<td>FOI</td>
<td>M11-M45</td>
<td>7</td>
<td>No approval needed/covered by experiment leaders. Mail from Christian Carling 02.10.15. Reiterated that no personal data is collected in email from Carling to Stine 16.10.2015. 24.1 &amp; 24.3 has been merged. Now called 24.1</td>
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<tr>
<td>T46.1</td>
<td>T46.1</td>
<td>FRQ</td>
<td>M12-M51</td>
<td>7</td>
<td>Mail from Jaime 2.10.15: WP46 will be restructured, and thus the approvals will be postponed. Date and time unclear, will be updated when restructuring process is over. As such 46.1 will be part of the next round of approvals.</td>
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<tr>
<td>T52.1 &amp; T52.2</td>
<td>T52.1 &amp; T52.2</td>
<td>FHG-IAG</td>
<td>M5-12/ M11-18</td>
<td>Application has been sent and forwarded to PRIO, but not approval received. German DPA says that they don't have any further comments on the documents submitted.</td>
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<tr>
<td>T61.1</td>
<td>T61.1</td>
<td>DLR</td>
<td>M15-M52</td>
<td>7</td>
<td>Answer from Carsten Dalaff: no data will be collected in 61.1; Mail from September in Folder</td>
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<tr>
<td>T64.1</td>
<td>T64.1</td>
<td>POLE</td>
<td>M18-M42</td>
<td>7</td>
<td>Application to DPA Forwarded to PRIO by Fernando 17.03.2015. Mail from Jaime/ Raul (both WP44 leaders) no reply yet received. Willi Wendt asked to update table and documentations and conduct review.</td>
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<tr>
<td>T53.1</td>
<td>T53.1</td>
<td>FOI</td>
<td>M12</td>
<td>8</td>
<td>E-Mail Exchange; Application submitted, but not authorization yet received by Pär Eriksson. Pär ’Eriksson 12.10.15: No further formal approval or authorization from the Swedish DPA (or similar) is needed for this activity, and that the attached documents are sufficient.</td>
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</table>

### 2014

<table>
<thead>
<tr>
<th>Task</th>
<th>New Task/ Changes</th>
<th>Lead Partner</th>
<th>Start activity</th>
<th>Application (M)</th>
<th>Mention in DoW</th>
<th>Application sent</th>
<th>Approval received</th>
<th>Comments (status before/ after restructuring)</th>
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</thead>
<tbody>
<tr>
<td>T34.2</td>
<td>T34.2</td>
<td>USTUTT</td>
<td>M13-M27</td>
<td>9</td>
<td>Has asked responsible authority in Germany about the procedure. DPA has replied and said that they only give generalized approvals. WP leader has been in contact with PRIO, but final notification (of USTUTT to DPA + reply) still needs to be sent to PRIO. Willi Wendt. German DPA got general description, the description will be updated with new information about collection of data for an end user list. Update will be sent in November. Reply is then pending. Potentially part of next round. Klyober email 09.10.15: This is not relevant any more. Activities in T36.2 (Experiments under 36.1) are led by USTUTT, see task above. Willi Wendt asked to update table and documentations and conduct review.</td>
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<tr>
<td>T35.4</td>
<td>T35.4</td>
<td>FRQ</td>
<td>M13-M36</td>
<td>Q4PR (Peter MacDonagh) is responsible for the task. Data collection starts later, and the application can only be sent when the research plan is ready late this year. Will be part of 95.24, but submission of this will happen 3 months before the work starts.</td>
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<tr>
<td>T36.3</td>
<td>T36.2</td>
<td>FRQ</td>
<td>M1-M36</td>
<td>9</td>
<td>Task is combined with 36.4. Mail from Ludwig from FRQ on 30.04 Oone application for 36.3 and 36.4 by FRQ. Application send and forwarded to PRIO 09.10.15 by Klyober. Application with supporting docs is filed in relevant folder. Confirmed by DPA</td>
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<tr>
<td>T37.2</td>
<td>T37.2</td>
<td>IRC</td>
<td>M15-M56</td>
<td>15</td>
<td>Not included in the application forwarded to PRIO by Fernando 17.03.2015. Mail from Jaime 2.10.15: WP46 will be restructured, and thus the approvals will be postponed. Update from Jaime 14.10.15: no news on this in this round, will be part of the next round.</td>
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<tr>
<td>T46.2</td>
<td>T46.2</td>
<td>ATOS</td>
<td>M12-M36</td>
<td>12</td>
<td>No approval needed. Mail from Christian Carling 02.10.15.</td>
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<tr>
<td>T53.1</td>
<td>T53.1</td>
<td>FOI</td>
<td>M+</td>
<td>Application received, cf. Folder 95.23 Application sent. Approval &quot;not needed&quot;</td>
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<tr>
<td>T66.1</td>
<td>T66.1</td>
<td>POLE</td>
<td>M18</td>
<td>14</td>
<td>Mangellavilla statement for 66.1: No data collected; Mail 3rd September in Folder</td>
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</tbody>
</table>

### 2015

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<thead>
<tr>
<th>Task</th>
<th>New Task/ Changes</th>
<th>Lead Partner</th>
<th>Start activity</th>
<th>Application (M)</th>
<th>Mention in DoW</th>
<th>Application sent</th>
<th>Approval received</th>
<th>Comments (status before/ after restructuring)</th>
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<td>T72.6</td>
<td>T72.6</td>
<td>M18</td>
<td>M11-M64</td>
<td>Indicated by Stephanie as needing approval after the restructuring. See email to Stine 16.12.2015</td>
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<td>T77.3</td>
<td>T77.3</td>
<td>ARTIFIC</td>
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<td>Indicated by Stephanie as needing approval after the restructuring. See email to Stine 16.12.2015</td>
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<td>Task</td>
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<tr>
<td>T25.2</td>
<td>Merge of former T73.1 and T85.1 MSB M19-M52 <strong>New task in the sheet. No personal data is collected according to email from Carling to Stine 15.12.2015.</strong></td>
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<tr>
<td>T25.3</td>
<td>Task removed in new DOW MSB M19 15</td>
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<td>T33.3</td>
<td>T33.4 DRC M19-M34 15</td>
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<tr>
<td>T32.4</td>
<td>T32.4 DRC M19-M58 15 <strong>New name: Support and care to volunteers</strong></td>
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<tr>
<td>T35.4</td>
<td>T35.4 APR M13-M58 <strong>Data collection starts later this year</strong></td>
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<tr>
<td>T46.1</td>
<td>T46.1 FR1 M12-M51 7 <strong>IMPORTED from round 2 - task postponed due to restructuring</strong></td>
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<td>T46.2</td>
<td>T46.2 ATOS M12-M56 11 <strong>IMPORTED from round 2 - task postponed due to restructuring</strong></td>
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<td>T53.2</td>
<td>T53.2 FOI M6-M18 14 <strong>New name: Effective Communication for public preparedness. IMPORTED from round 2 - task postponed due to restructuring</strong></td>
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<tr>
<td>T52.3</td>
<td>T52.3 FIN-JAO M18-M56 10 <strong>Might be needed later</strong></td>
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**2016**

<table>
<thead>
<tr>
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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T34.3</td>
<td>T34.3 POLE M25-M39 21 DOW mentions Task 34.5 under ”research ethics compliance” but description of T34.5 is nowhere to be found! --&gt; T34.5 did never exist, so I hope we can forget about that ”red” aspect. mail Wolf Engleback 11/09/2014</td>
</tr>
<tr>
<td>T34.4</td>
<td>T34.4 FIN-JAO M25-M52 21</td>
</tr>
<tr>
<td>T36.4</td>
<td>T36.4 AIT M25-M52 21 <strong>covered by 36.3</strong></td>
</tr>
<tr>
<td>T33.4</td>
<td>T33.5 TNO M25-M52 21 <strong>Authorization Received 9 September (sent by Maike to Anne D)</strong></td>
</tr>
<tr>
<td>T35.2</td>
<td>T35.2 FIN-JAO M34-29 19 <strong>No approval needed; Mail from Maike Vollmer to Mareile and Anne on 09.10. After restructuring. Still called ”standardization activities.”</strong></td>
</tr>
<tr>
<td>T46.3</td>
<td>T46.3 DHI M25-M52 21</td>
</tr>
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<td>T54.2</td>
<td>T54.2 TNO M8-M46 21</td>
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<td>T54.2</td>
<td>T54.2 TNO M51-M58 21</td>
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<td>T54.4 NO M52-M58 21</td>
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<tr>
<td>T64.3</td>
<td>T64.3 M8 M32-M39 28</td>
</tr>
<tr>
<td>T65.1</td>
<td>T65.1 M22-M30 28 <strong>New name: Assessment methodology</strong></td>
</tr>
<tr>
<td>T55.2</td>
<td>T55.2 DRC M6-M46 26</td>
</tr>
<tr>
<td>T65.3</td>
<td>T65.3 ITI M28-M36 29 <strong>Email from Pär Eriksson 12.10.2015 that as similar procedure as for T53.1 (round 2) will be used: using a statement from the DATA PROTECTION OFFICER and then an informed consent form of a similar kind for the participants.</strong></td>
</tr>
<tr>
<td>T53.4</td>
<td>T53.4 EDI M28-M56 29 <strong>Email from Pär Eriksson 12.10.2015 that as similar procedure as for T53.1 (round 2) will be used: using a statement from the DATA PROTECTION OFFICER and then an informed consent form of a similar kind for the participants.</strong></td>
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<tr>
<td>T55.1</td>
<td>T55.1 TNO M8-M46 29</td>
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<td>T55.2</td>
<td>T55.2 DRC M6-M46 29</td>
</tr>
<tr>
<td>T65.1</td>
<td>T65.1 M22-M50 28 <strong>Indicated by Adrien in email to Stine 17.12.2015. Dalaff, Carsten update 17.12.2015: T64.3 is called ”Experiment execution”. Now merged with T64.4.</strong></td>
</tr>
<tr>
<td>T65.2</td>
<td>T65.2 M22-M41 29 <strong>Indicated by Adrien in email to Stine 17.12.2015.</strong></td>
</tr>
<tr>
<td>T53.3</td>
<td>T53.3 DRC M28-M36 29 <strong>Indicated by Adrien in email to Stine 17.12.2015.</strong></td>
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<td>T55.1</td>
<td>T55.2 FOI M22-M50 28 <strong>Indicated by Adrien in email to Stine 17.12.2015.</strong></td>
</tr>
<tr>
<td>T56.4</td>
<td>T56.4 FOI M40-M46 30 <strong>Indicated by Adrien in email to Stine 17.12.2015. Dalaff, Carsten update 17.12.2015: T64.4 - task called: ”Evaluation Final Demo”</strong></td>
</tr>
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</table>

**Might be needed later**

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T35.3</td>
<td>T35.5 STUTT M7-M27 1 <strong>&quot;Nothing is planned this year, so we better ask when the experiments are better defined&quot; mail Wolf Engleback 11/09/2014. New name: Effective Public Alerting</strong></td>
</tr>
</tbody>
</table>
Important note:
Once the suspension is lifted, this table will have to be updated and aligned with the new content and planning of the project.

This revision is foreseen to happen before the next round of ethical approvals is due in M30 (October 2016). It is also clear that the responsibility for updating remains with PRIO, and making sure that the appropriate approvals are in place for the relevant research activity, lies with the task leader and not with PRIO.
7 The 10 DRIVER rules for informed consent and data protection

Before applying for approval at the Data Protection Authority of where the data is collected and processed, the most important rules for informed consent and data protection, which comply with the current EU data protection directive 95/46/EC, has to be taken into account. The summary of these crucial rules below provides for an overview of the core duties of the researcher.

1. **Process lawfully.**
   Follow the local law for processing the data of the country where the data is gathered.

2. **Make sure to get informed consent.**
   Be clear, open and transparent with your research participants. Explain well what for and how the data is gathered, stored, used and processed (also between countries). Avoid unnecessary jargon. Make sure that participants are not only well-informed, but also can decide freely whether they would like to participate in the research or not. You should prepare this information on a written 1-page information sheet that should be signed by the participant. Any use of sensitive data will need to require signed informed consent forms that the principal researcher needs to keep.

3. **Process fairly.**
   If you use data from other research projects, you are still required to provide the individual participants with the prescribed information unless doing so would involve a disproportionate effort. This exemption is unlikely to apply where you have the individuals’ contact details, or access to them, regardless of the number of participants involved.

   Secondly, there is the general duty to process personal data fairly. This requires research teams to consider more generally how their use of personal data affects the interests of the individuals to whom it relates. In circumstances where your use may cause detriment to an individual, you need to consider whether or not that detriment is justified (see comments on the sixth data protection principle below). [1: p.6]

4. **Make sure that you use your collected data only for the purpose you specify to the participants.**

5. **Avoid collecting unnecessary data. Only collect data that is proportional to the purpose.**
Proportional means here that you should only collect personal data that is strictly necessary for the purpose of the research you conduct, not more and not less. This applies to both, the amount and the content of data.

6. **Don’t process data that is not up-to-date.**

Where data is not kept up-to-date it may cease to be adequate and relevant for the purposes for which it is to be processed. Accordingly, its retention will be excessive. If you create static archives, updating would defeat the purpose. [1: p.8]

7. **Don’t keep the data longer than necessary.**

Data that is no longer needed for the purpose for which is was collected, should be deleted.

8. **Process in accordance with individuals’ rights.**

Individuals have (a) a right of access to personal data held about him; (b) a right to prevent processing of personal data which is likely to cause damage or distress to the individual; (c) a right to prevent the processing of personal data for the purposes of direct marketing; and (d) a right to require that no decision which significantly affects the individual is based solely on automatic processing of personal data [1: p.9].

9. **Gather, process and store data securely.**

It should be noted that the requirements of the Act go beyond the way information is stored and transmitted, relating to every aspect of the processing of personal data. Security measures should seek to ensure that: (a) only authorised people can access, alter, disclose or destroy personal data; (b) those people only act within the scope of their authority; and (c) if personal data is accidentally lost or destroyed it can be recovered to prevent any damage or distress to the individuals concerned [1].

Make sure to anonymize data where necessary. Remember that in an aggregated format, it is easier to deduct information about a person. If you gather video, audio or other visual data (e.g. from Drones, Facial Recognition Technology etc.), anonymization is often impossible. Getting informed consent of participants is here even more important.

For some projects it is a requirement that data is stored for a long time. Make sure that the data is stored securely and proportionally to the purpose, meaning: don’t collect too much or insufficient data, or data that does not answer the purpose of your research.

The physical security of personal data includes factors such as the quality of doors and locks and whether the premises are protected by alarms, security lighting or CCTV; but it also includes how access to the premises is controlled, the supervision of visitors, the disposal of paper waste and the
security of portable equipment (e.g. laptops and any storage media or devices). Computer security is constantly evolving and may require specialist advice. Make sure to use encryption and password protection where necessary [1].

It is important to understand that where a research team uses any third party to process personal data on its behalf, for example conducting interviews on another institute’s behalf, the Institute will be held responsible for any breach of the obligations under the Act by that third party. Moreover, there are a number of conditions which apply to the use of such third parties (see section H), including a written contract requiring them to comply with obligations equivalent to those imposed by the seventh data protection principle [1].

10. **Make sure not to transfer data to countries outside the EEA.**

It is not only important to keep these rules in mind, but also to apply for approval at your local Data Protection Authority.
8 How to obtain approval

The principal researcher of the task will have to apply for approval at the relevant local authority, such as Data Protection Authorities or other ethical authorities or committees. The principal researcher is in control of and legally responsible for the collected data.

When preparing the approval application, principal researchers should pay attention to:

- how they will inform the participants and how these participants can and will give their informed consent,
- how the data is collected (audio-recordings, visual recordings, notes, transcripts etc.),
- what kind of data is collected and how it contains personal data (that potentially leads to the identification of an individual),
- whether and how the data is anonymised,
- how and where the data is stored and whether it is password-protected,
- who has access to the data (also in terms of data-sharing),
- how and when the data will be destroyed after the project is finished.

In Norway, for example, the Norwegian Social Science Data Services asks the following questions in order to assess whether a project meets the necessary requirements for approval. This list is extensive, but not exhaustive as it may look different in each country. It is supposed to guide you to a good description of your planned research. The answers do not need to be long. Any question answered positively will need an explanation or specification. While answering these questions, please keep in mind DRIVER’s rules for informed consent and data protection (Chapter 8).

More information about research ethics and the procedure to obtain approvals can be found in D91.3.

8.1 General information

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

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17 All questions are either quoted from or inspired by [2 : Notification Form]
8.2 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?

8.3 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

8.4 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.” [1: p.4])
- 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?
8.5 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).

8.6 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.

8.7 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.

8.8 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?
9 Integration of ethics in the DRIVER experiments

Since the DRIVER experiments will be conducted at a later stage during the project and since the planning for these is still underway, the monitoring for ethical approval foresees a second information initiative later in the project when schedules and methodologies are settled. A specific section of D91.3, as well as the workshop on research ethics given to the DRIVER General Assembly during the DRIVER meeting week in Ispra in 2015, is and was also dedicated to discussions on how to get ethical approvals, also from ethical authorities other than DPAs.

9.1 Preliminary key questions for the DRIVER experiments

For each research, experiment, testing or demonstration activity, the following four questions should be answered:

Q1: Is the research, experiment, testing or demonstration activity carried out by human individuals whose safety or well-being may be compromised by the activity?

All activities carried out by humans that may cause physical, psychological, emotional or similar impact to those carrying it out are subject to ethical assessment. Such tasks should be designed carefully and described in detail in a written application to the relevant local ethics advisory board.

Q2: Does the research, experiment, testing or demonstration activity involve human individuals whose safety or well-being may be compromised as a secondary impact of the activity, i.e. as bystanders, knowingly or non-knowingly?

All research, experiments, testing or demonstration activities that might cause negative secondary impact, through physical, psychological, emotional or similar impact to bystanders, or that might harm the environment, economic conditions, human development in general, etc. should be designed carefully and described in detail in a written application to the relevant local ethics advisory board.

Q3: Does the research, experiment, testing or demonstration activity involve the collection of data from human individuals, regardless of whether they are aware or not?
All research, experiments, testing or demonstration activities that involve human participants, that is, human individuals participating in a direct way by answering questions about themselves or their opinions, or performing tasks, or being observed, or which involve data about identified or identifiable individuals should be designed carefully with respect to the way the collect, process, analyse and store personal data should be described in detail in a written application to the relevant local ethics advisory board.

**Q4: Does the research, experiment, testing or demonstration activity involve the processing of data collected from human individuals?**

All research, experiments, testing or demonstration activities that involve the possession or handling of personal data should be described in detail in a written application to the relevant local ethics advisory board.

By **handling of personal data** we mean anything a researcher does with personal data, including obtaining it, holding or storing it, retrieving, consulting or using it, organising or adapting it, publishing, disclosing or sharing it, and even destroying it.

### 9.2 Questionnaire about Data Protection

This brief questionnaire is a first step for any individual or organization planning a research activity, for determining which data protection issues that are or might be relevant for the activity at stake.

For each research activity, we propose that the following questions are answered:

**Q1: Does the research activity involve the collection of data from human individuals, regardless of whether they are aware or not?**

All research activities that involve human participants, that is, human individuals participating in a direct way by answering questions about themselves or their opinions, or performing tasks, or being observed, or which involve data about identified or identifiable individuals should be designed carefully with respect to the way the collection, processing, analysis and storage of personal data, which should be described in detail in a written application to the relevant local ethics advisory board.

**Personal data** refers to practically all forms of information that a researcher might hold. However, it should be noted that data protection principles are primarily concerned with information which is (a) held, or intended to be held, on computer; or (b) held in manual records which are sufficiently structured so as to allow ready access to specific information about individuals. Personal data is information which relates to a living individual who can be identified (a) from those data; or (b) from those data and any other information which is in the possession of, or likely to come into the
possession of, anyone who may have access to it. This includes any expression of opinion about the individual and any indication of the intentions of any person in respect of the individual. The information does not have to be factually correct in order to be personal data. A person’s identity can, for example, be obtained directly from identifiers such as names, addresses, postcode information, telephone numbers or pictures, or indirectly from identifiers which, when linked with other publicly available information sources, could identify someone, e.g. information on workplace, occupation or characteristics like salary or age.

Please keep in mind that if workshops are conducted, data is recorded or a participants list is kept to reimburse participants afterwards, all of this is potentially identifiable personal data.

**Q2: Does the research activity involve the processing of data collected from human individuals?**

All research activities that involve the possession or handling of personal data should be described in detail in a written application to the relevant local ethics advisory board.

By handling of personal data we mean anything a researcher does with personal data, including obtaining it, holding or storing it, retrieving, consulting or using it, organising or adapting it, publishing, disclosing or sharing it, and even destroying it.

In the course of the first two years of DRIVER, several documents and mails have been sent to the DRIVER partners to outline the steps of identifying whether and how to get ethical approval. An example of such an informative effort can be found in the annex to this deliverable. The concrete effort was followed up with regular mailings.

For more detailed explanations and a step-by-step introduction on whether and how to obtain approval, please be referred to D91.3, Chapter 5.
10 Concluding remarks & further support

All DRIVER partners will have to follow the process outlined in this deliverable to obtain ethical approvals in time. The schedule provided in this deliverable is indicative of the foreseen timing for these approvals. Chapter 9 provides a step-by-step procedure/questionnaire that can be followed when applying for ethical approvals at the local data protection agency. Every partner is responsible to obtain the approvals that concern the task her or she leads. PRIO is merely monitoring the process.

PRIO will be available to all DRIVER partners for answering questions about research ethics, especially as the PRIO partners continue to update themselves about the different research activities that will be conducted throughout the project. Despite that, DRIVER partners are expected to report any changes in the planned research to PRIO, as long as this influences or refers to the process of getting ethical approvals.

In order to get answers on concrete questions about the content of the ethical approval-applications it is necessary that the primary researcher who is responsible for conducting the actual research identifies the local authority that he or she is applying to. These authorities will be able to inform partners about the specific requirements needed for approval in the respective country.

If more advice is needed: Together with other ethics experts does Dr. Katerina Hadjimatheou, member of the DRIVER Ethical Advisory Board, organize the SURVEILLE Ethical Advisory Service, which can also be consulted to obtain objective and confidential advice on questions about research ethics. More information can be found here: www.surveilleadvisoryservice.eu

*D95.21 has introduced the key principles of Special Clause 15 and the legal requirements of getting such approvals. It explained the two-stage information procedure that is used to monitor the acquisition of such approvals for the full consortium, which first focuses on interview-based research and at a later stage focuses on experiments.*
References


Dear DRIVER partners,

As you know, research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. For research carried out in European projects these standards are derived from the European Convention of Human Rights, the European Charter of Fundamental Rights and the Treaty of the European Union in general, in addition to a range of relevant directives, communications, and executive orders, in particular the European Directive 95/46/EC for the protection of personal data. These obligations are not merely ethical in nature, they are contractual. They are imbedded in the Grant Agreement of the DRIVER project in a variety of ways, most prominently through the general contractual mechanism put in place in order to assure this high standard of research ethics, known as Special Clause 15. You have already received detailed information on this through deliverables 91.3 and 95.21.

PRIO has set up a table indicating all the expected tasks needing approvals (see D95.21, Section 5). All partners need to make sure that they apply for ethical approval at their local Data Protection Authority. Below, you will see an overview of all tasks that are likely to need an approval up until M18. At least those partners indicated in the table’s schedule need to respond to PRIO at the indicated points in time. This table is an orientation based on PRIO’s estimates. It is thus each partner’s duty to notify PRIO if they plan any research that involves data collection and may need approval, but is not listed in the table yet. A new table for the next round (M19-M30) will be circulated after M18. Approval needs to be applied for by the principal researcher organisation of the research done (in most cases the task leader), who takes full legal responsibility for the collection and potential storage of data. In case no particular guidelines for this procedure are given by your local Data Protection Authority, please see D95.21 Section 7 for a suggested template for writing approval applications.

| Annexes: Example letter to the DRIVER consortium about approval process |

Oslo, 24.04.2015

FP7 Project DRIVER: Ethical Approvals

Dear DRIVER partners,

As you know, research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. For research carried out in European projects these standards are derived from the European Convention of Human Rights, the European Charter of Fundamental Rights and the Treaty of the European Union in general, in addition to a range of relevant directives, communications, and executive orders, in particular the European Directive 95/46/EC for the protection of personal data. These obligations are not merely ethical in nature, they are contractual. They are imbedded in the Grant Agreement of the DRIVER project in a variety of ways, most prominently through the general contractual mechanism put in place in order to assure this high standard of research ethics, known as Special Clause 15. You have already received detailed information on this through deliverables 91.3 and 95.21.

PRIO has set up a table indicating all the expected tasks needing approvals (see D95.21, Section 5). All partners need to make sure that they apply for ethical approval at their local Data Protection Authority. Below, you will see an overview of all tasks that are likely to need an approval up until M18. At least those partners indicated in the table’s schedule need to respond to PRIO at the indicated points in time. This table is an orientation based on PRIO’s estimates. It is thus each partner’s duty to notify PRIO if they plan any research that involves data collection and may need approval, but is not listed in the table yet. A new table for the next round (M19-M30) will be circulated after M18. Approval needs to be applied for by the principal researcher organisation of the research done (in most cases the task leader), who takes full legal responsibility for the collection and potential storage of data. In case no particular guidelines for this procedure are given by your local Data Protection Authority, please see D95.21 Section 7 for a suggested template for writing approval applications.
Please note that without approval, collected data cannot be used, meaning you cannot start your research. Before starting your research, the REA Project Officer needs to receive a copy of the approval.

As set out in Task T95.2, PRIO is responsible for collecting the needed authorisations. However, the responsibility for obtaining such authorisations falls to the concerned organization and the task leader. In order to monitor the progress of the authorisations your organization is expected to need, please find below the list of tasks we have identified as potentially needing an authorisation until October 2015:

<table>
<thead>
<tr>
<th>Task</th>
<th>Task partner</th>
<th>Start Activity</th>
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<tbody>
<tr>
<td>T32.2</td>
<td>DRC *</td>
<td>M4</td>
</tr>
<tr>
<td>T32.3</td>
<td>DRC *</td>
<td>M4</td>
</tr>
<tr>
<td>T36.2</td>
<td>USTUTT</td>
<td>M10</td>
</tr>
<tr>
<td>T36.2</td>
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<tr>
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</tr>
<tr>
<td>T46.1</td>
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</tr>
<tr>
<td>T66.1</td>
<td>POLE</td>
<td>M18</td>
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</table>

Please check first, if the task indicated needs an approval. When in doubt, send a short mail to PRIO explaining what you intend to do. If you need approval:

- Send us a copy of the approval
- Annex the application form you have sent to your DPA
- Clearly state in your response letter to which task this approval applies
• It is possible to combine similar tasks with the same leaders in order to obtain 1 approval for all of them. If the approval concerns several tasks clearly state which ones (even if they were not on the list) and justify why they are similar enough, explain who takes the lead.

When you have applied for an approval but have not received the approval, for example because the authorities do not deliver them or because only notification is required:

• Send us the application form/notification you have sent to your DPA
• Clearly state in your response letter to which task(s) this application/notification applies

When you consider the indicated task doesn’t require an approval:

• Clearly state in your response letter which task and why such approval is not needed
• If another partner should obtain the approval, indicate who
• If the approval is needed but at a later stage, please specify when so that we can do the follow-up in due time.

When you consider tasks not mentioned in the table as potentially needing approval, for example if the activity of a task changes:

• Notify PRIOR
• Apply for approval as per procedure above

We need to receive your signed response letter before the start of the activities mentioned in the list. In case we do not receive an answer from you by then, we will have to inform the Project Officer accordingly. This would mean that you will not be authorised to start your activities in the said task.

In sum:

• The task leaders have to obtain the needed approvals
• If tasks indicated in the table does not need approval, a short statement why should be sent to PRIOR
• If the timing of relevant activities change, PRIOR should be notified to adjust the table accordingly
• Approval needs to be in place before the research activity starts
• Please send you approvals to Anne Duquenne (annduq@prio.no), cc’ing Stine Bergersen (stiber@prio.no) or Mareile Kaufmann (markau@prio.no).

When in doubt, please consult the aforementioned deliverables, your local DPA or after doing so contact PRIOR.

Warm regards,