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

D91.3 – Ethical Procedures, Risks and Safeguards

Grant agreement number:	607798	Due date of deliverable: 2014-10-31
Start date of the project:	2014-05-01	Actual submission date: 2014-10-30
Duration:	54 months	

Lead Beneficiary: PRIO

Contributing beneficiaries: FhG-INT, ECORYS

Keywords:
Ethical Approvals, Ethical Considerations, Informed Consent

Dissemination level:	
PU	☒
PP	☐
RE	☐
CO	☐

Release Number	Release date	Released by
0.1	17. October 2014	Stine Bergersen, Mareile Kaufmann, Merle Missoweit
0.2	24. October 2014	Linette de Swart, Brigitte Slot, Laura Birkmann
0.3	27. October 2014	Gerry Foitik
1.0	29. October 2014	Stine Bergersen, Mareile Kaufmann, Merle Missoweit

Executive Summary

There are many considerations to take into account when conducting research. Ethics should be applied to all stages of research, including planning, conducting and evaluation. It is important to know and obey relevant laws and institutional and governmental policies (e.g. obtaining commitment and authorizations in the preparation phase), but furthermore, the effectiveness and credibility of research cannot be maintained without carefully weighed consideration and active implementation of ethical standards. Ethics in research encompasses both, ensuring good scientific practice (i.e. researcher ethics) and safeguarding individuals and even society at large (i.e. research ethics)[1]. Here we focus on the ethical sides of the research methodology in relation to DRIVER experiments, e.g. the importance and quality of informed consent. Other issues, such as data protection obligations (Special Clause 15) are assessed in more detail in D95.21, but will also be described here.

The annex contains templates for **Informed Consent Forms** and **Research Ethics Approval Applications**. A powerpoint presentation with the most important principles and advice will be circulated with the Deliverable. This presentation is also included in Annexes.

[1] The National Committee for Research Ethics in Science and Technology) (NENT): *Forskningsetisk sjekkliste*.

Table of content

List of Acronyms

Abbreviation / acronym	Description
CCTV	Closed Circuit Television (Surveillance Cameras)
Cf.	See
CM	Crisis management
D	Deliverable
DoW	Description of Work
DP	Data Protection
DPA	Data Protection Authority
FD	Final Demo
FP7	Framework Programme 7
JE 1 & 2	Joint Experiments
NESH	Norwegian National Committees for Research Ethics
REA	Research Executive Agency
SC 15	Special Clause 15 in the Ethical Guidelines of the FP7 agreements
SE 1 & 2	Subproject Experiments
SP	Subproject
UN	United Nations
WP	Workpackage

1 Introduction

All research conducted within the scope of DRIVER is subject to ethical considerations, especially if the research activities potentially come into conflict with commonly recognized values. This deliverable aims at providing useful guidelines and recommendations for responsible research conducted in DRIVER, especially with regards to scientific aims, assumptions, methods, and expected results. It will do so by presenting and clarifying the relevant ethical considerations to be taken into account when conducting interviews, focus groups, and especially experiments. Throughout the document, recommendations for ethical research will be provided in text boxes at the end of the relevant paragraphs. These are summarized in Chapter 5, the DRIVER Ethical Research Recommendations.

At the core of this Deliverable are the DRIVER experiments, which can include a range of activities within DRIVER, meaning anything from interview and workshop sessions to acting out a scenario (for an overview of the term experiment see Chapter 3.2), all of which is covered in this deliverable. Because the term “experiment” is rather common, also in everyday language, and relates to a number of things in the DoW, it is important to use this term with care. In the DRIVER DoW, experiments are mentioned as involving methodologies (in WP22) and states that an experiment can also include “just interviews” or “data collection”, which will be the main research activities in SPs 3, 4, and 5. The CM-solutions developed in SPs 3-5 will feed into more complex experiments conducted in SP6, using a test bed provided by SP2. As opposed to the smaller experiments conducted within SP 3-5 (SE1 and SE2), the joint experiments are anticipated to be more advanced in terms of complexity and operational realism. The latter may require attention beyond data protection which will be elaborated in 3.2.

In SP6 (referred to as the heart of DRIVER) two parallel joint experiments are conducted (campaigns of experiments) followed by a final demo. The campaign of experiments consists of a series of experiments in which typically a cluster of promising ideas are tested, assessed and benchmarked in realistic conditions with real users, sequenced so that each experiment provides an additional step towards a refined operational solution. Implementation and testing of the DRIVER portfolio of crisis management tools happens in three fictitious contexts:

- Joint Experiment 1 (JE1): Flooding with follow-on pandemic
- Joint Experiment 2 (JE2): Major ice storm with power and ICT failure
- Final Demo (FD): Mediterranean tsunami with add- on hazards

Both experiments and the demo will cover all levels: local, regional, national and pan-European level and (in parts) UN-level and also all levels of decision-making from operational to strategic. They will involve end -users with their legacy systems, citizens and volunteers, the DRIVER test-bed from SP2

(platforms, test-bed tools, methods, people and ideas[2]) and solutions based on experimental research from SP3-5.

In conclusion, "experiments" can mean a number of things, and must be considered in specific cases. This deliverable covers ethical procedures, risks and safeguards for experiments in the sense of interviews, workshops, testing of tools and tablet of exercises. This deliverable will give advice about the research to be conducted in SPs 3-5, and also aspects that will be relevant in SP6/2. Section 3.2 will address the questions of experiments specifically.

Chapter 1 explains the relation of this deliverable to 95.21 that already covers the basics of research ethics, Chapter 2 introduces general research ethics principles, Chapter 3 introduces risks and procedures with a specific focus on the collection of personal data and experiments in DRIVER, Chapter 4 gives an overview over safeguards & principles, Chapter 5 provides a checklist of recommendations for DRIVER partners. The annex contains templates for **Informed Consent Forms** and **Research Ethics Approval Applications**. A powerpoint presentation with the most important principles and advice will be circulated with the Deliverable.

1.1 The Relation to D95.21

This deliverable draws on input from, and serves as a supplement to D95.21, where the plan for the monitoring of getting the relevant approvals subject to Special Clause 15 (SC15) is described. This overlap can be explained by the fact that the information process about research ethics was needed at an earlier stage in the project, since data collection and data processing was already being planned from M1 onwards. This created the necessity to clarify and state the most relevant ethical principles and procedures already in D95.21, which was submitted in June 2014. However, this deliverable further explores the concept of research ethics, and sensitizes the consortium towards useful and applicable ethics.

1.2 The Scope and Limitations of 91.3

This deliverable does not aim at providing the consortium with the guidelines for the general approvals and insurances (from law enforcement, official agencies etc.) needed to conduct experiments. This deliverable is exclusively about potential *ethical* approvals needed, and *other ethical considerations* to mitigate risks and safeguard key ethical principles for conducting research.

[2] cf. D13.31 for definitions.

2 General Research Ethics Principles

2.1 Why Research Ethics?

Research carried out under the aegis of European Commission funded projects is expected to maintain high ethical standards. The reason this is important is because the rationale behind these ethical rules and principles includes certain safeguards that, if not upheld, would put the very foundation of research at risk. Safe and sound research activities contribute to accountable and legitimate research outputs. Some research activities within DRIVER will be subject to approvals regulated by Special Clause 15, such as most interviews and experiments (e.g. experimental tests of crisis management solutions, table-top exercises, and workshop-like activities). Within FP7 projects, Special Clause 15 regulates the collection and processing of personal data, which means that any research involving personal data is subject to approval by the data protection authorities (DPAs) of the country in which the data is collected (cf. Annex 2). D95.21 already informs the consortium about the different points in time when the research activity subject to such approvals take place (see for example D95.21 Chapter 5).

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

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

In the following paragraphs, some main practical implications of Special Clause 15, derived from D95.21 are explained.

As Special Clause 15 applies to all forms of research, experimentation, testing and demonstration, this means that wherever human beings are involved in research activities, measures are to be taken to ensure their safety and wellbeing. Safety and wellbeing applies to those individuals who might be indirectly impacted by the research, and to those human beings that might be objects of the research through direct study, indirect observation, interviews, data collection or other means, but it also applied to the researchers carrying out the research. 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. This means that any research needs to be reviewed with regards to their need for approvals. For that, D95.21 provides guidelines and Chapter 3.2 of this deliverable.

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

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

All three of the ethical risk areas engage the principle of informed consent (see 3.3 and 3.3.1. for more information on this). Whether involved in the research as a researcher, a bystander or an active participant in the research, individuals have the right to be informed and fully understand the research in which they are involved. We will address these questions in depth below.

2.2 Research Ethics as a Question of Methodology

Research ethics refer to questions of methodology. A thorough planning of the experiments, for example when designing scenarios or questionnaires, is to design them as realistic and as targeted as possible in order to reach the goal of experiments, reduce complexity and reflect on the potential shortcomings of the selected method. It is thus important to contemplate how the output of an experiment is limited by the used methodology, the selected population and the specific conditions of the experiment. In addition to that, what you observe when conducting an experiment is highly influenced by what you expect to find or even what your employer expects you to find (principal-agent-problem). It is important to reflect on these preconditions when reporting and discussing the results of an experiment. In DRIVER, in contrast to other FP7 demonstration projects, research activities are designed to not just demonstrate, i.e. proof a given concept, but to conduct real experimentation that either (i) seeks to falsify the hypothesis of the added value of a tool for Crisis Management or (ii) tries to detect hitherto unknown phenomena of the Crisis Management process that emerge when new tools are added and combined with each other or legacy systems. Both types of experiments will be conducted while applying strict methodology (cf. WP23) that includes performance indicators and metrics as well as control of variables that could have an unpredictable outcome on the experiment. Only the final demonstration will have the notion of a proof of concept, however, still under application of the developed methodology in order to minimise expectation-bias of the researchers involved.

Another potential challenge concerning experimental research has to do with validity. Experiments are rarely reproduced, because they might be very expensive, or simply because the interest in the research has worn off as it has been done before. The ideal following good research ethics is to repeat important experiments in order to detect potential skews or flaws in the design of the research or in the findings of the researcher. Testing tools and procedures throughout the whole projects thus increases the validity of the research results.

Regarding methodology, the Norwegian National Committees for Research Ethics (NESH) has raised some “red flags” that are also valid for conducting of experiments:

- The research could have a questionable or immoral starting point and / or ambition.
- The research could infringe upon the integrity of the research subjects.

- The results of the research could be too general or rooted in too far-reaching claims about reality.
- Research could be influenced by "wishful thinking".
- The researcher needs to be aware of the limitations of the research results.

2.3 General Practical & Ethical Considerations

This section provides practical and ethical guidelines for conducting research (and in particular experiments). When addressing ethical questions, several rules and principles need to be strictly upheld, such as the principles of the European Convention of Human Rights[3], the rules of the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data and for the protection of personal data, especially the European Directive 95/46/EC39, the details of which can be found here[4]. In addition, all relevant national legislations about data protection need to be followed, which includes getting the required approvals from the national Data Protection Agency (DPA) or similar institutions (for template cf. Annex 2). Task 85.3 (led by ECORYS) in DRIVER acts as a legal and regulatory advisor with regards to experimental research (including insurance issues, loss of wages for civilians, liability etc.), and implementation of CM tools (safety and data security etc.)

Recommendation → Collect and process data in line with Data Protection Regulations.

As long as research activities involve human participants in any way, some special considerations need to be taken into account (see 3.2.1 for more information). This involves issues regarding **data protection**, as well as the individual rights and principles as set out by the Special Clause 15 in the FP7 guidelines.

Transparency, validity, neutrality and accountability are central principles for conducting research, and need to be upheld in all stages and parts of DRIVER. They form the basis of each research step. While transparency and neutrality refer to an honest and open research process, validity and accountability refer to the results deriving from such a process, namely responsible and sound research outputs (see 2.2 and WP23 for how DRIVER seeks to minimise the lack of these principles). Other general and related principles are honesty, objectivity and openness, which are particularly important when informing research participants or consumers of research about the way in which the research is and was conducted.

[3] http://www.echr.coe.int/Documents/Convention_ENG.pdf

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

Recommendation → Follow a transparent research process based on neutrality in order to produce valid and accountable research results.

When the research involves human participants that enact a specific situation, it is important to make sure that neither the participants nor any secondary bystander risks being harmed or hurt, neither psychically or psychologically (more on this in 3.2.1). The project has to comply with national (or international) law on these matters (e.g. the regulations concerning the welfare of animals, or regulations on biological tests). In DRIVER, **task 85.3 will deal with legal provisions** that potentially have to be kept in mind when conducting research activities. Legal regulations include of course that research activities should never cause any damages to public or private properties, even though liability insurances exist. This is particularly relevant for experimental research that might take place in public space.

Another important rule for conducting research - and experiments in particular, is the duty to **inform the public** about the activity. If large exercises (potentially most relevant in SP6) take place in public space or in proximity of populated areas, the public must be informed about such exercises in order to avoid confusion and unease. In addition to all the relevant approvals that you need prior to such an exercise (e.g. medical personnel and insurance, authorizations by the police etc.), it is necessary to have an information and communication plan for bystanders in surrounding areas being affected by such an exercise, both by seeing unusual activities, but also by not being able to access this space in their usual manner. This depends on the content and shape of research experiments. The more unusual an experiment or exercise appears within one neighbourhood, local community, city etc., the more obliged are the arrangers of this experiment to inform the public. In addition, the stronger the public dimension of the experiment, the more important is a thoroughly planned information package. Such tasks will be met by the DRIVER dissemination team (WP75).

Recommendation → Have an information plan in place to inform the public, especially prior to public experiments.

Another general issue within research ethics is the **dual use**, or military application of the experimental research. Strict attention needs to be paid to verify whether the research results, the developed tool, measure or technology could be re-used for military application – even though this was unintended. The potential for malevolent abuse of technology always exist, almost regardless of the safeguards implemented to avoid it. In the particular case of DRIVER, the technology or outputs of the project may allow for manipulation by individuals with dishonest intentions, e.g. the interception of information about vulnerabilities, which not only could put individuals at risk, but

could also have an impact on the crisis situation as a whole. It is important to recognize this risk (a risk that in fact the development and use of all technologies face), and aim at keeping these risks at a minimum by for example drawing on the available expertise from both the stakeholders and the technology developers and by constantly evaluating for which purposes such tools and measures are being developed. The DRIVER Security Assessment Committee (FOI, FHG-INT, Pole, EUSC; cf. DoW, part B) will assess the sensitivity of DRIVER work in this regard and advice the team upon publication.

Other ethical issues and risks are connected to finances. When the research activity is conducted with or within countries with low-income or lower-middle income economies[5], it is also important to make sure that all the partners have **equal shares of the finances** in the project, meaning that the expenses are proportional between the partners, and should be adjusted to the real costs and expenses. This is, however, generally ensured by the evaluation of the proposal and the project reporting to the commission.

Recommendation → Ensure financial equality in research projects.

In sum, the main principles to be followed to ensure ethical research are summarized below.

→ **Principles to ensure ethical research are:**

- Transparency;
- Legality;
- Validity;
- Neutrality;
- Accountability;

→ **The following considerations should be taken into account:**

- Respect data protection;
- Do not inflict harm on humans and animals, or the environment;
- Respect national law, public and private property (cf. 85.3);
- Inform the public;
- Minimize dual use;
- Provide equal shares of the finances.

[5] http://data.worldbank.org/about

3 Risks & Procedures

Sources of data vary with the methodologies that are being applied within DRIVER. The most common sources of data within DRIVER derive from reports and datasets, data gained from interviews, workshops and the testing of tools and also data gained from larger experiments within DRIVER. The next two parts will focus on the two main aspects that are important to keep in mind when conducting research ethically within DRIVER: the collection of personal data and the collection of data from experiments. Both of them don't have to be mutually exclusive.

3.1 Collection of Personal Data within DRIVER

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

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

- directly from identifiers such as names, addresses, postcode information, telephone numbers or pictures,
- indirectly from identifiers which, when linked with other publicly available information sources, e.g. information about workplace, occupation or characteristics like salary or age. If workshops are conducted, data recorded or a participants list is kept to reimburse participants afterwards, all of this is potentially data that may identify a person.

For example, one potential source of data is data collected by airborne sensors during experiments in SP4 or SP6. These may collect vast amount of data that can potentially be used for identifying individuals. However, it is not possible to collect informed consent from every citizen that might fall under the scope of such a tool, and this makes it important to minimize potential harms and risks in connection to this procedure. Ensuring the right procedures for collecting and processing data is here of utmost importance. Thought need to be given to the way in which principles, such as Privacy by Design can be implemented.

Recommendation → Implement Privacy and Security by Design wherever possible.

3.2 Experiments Conducted Within DRIVER

In our everyday understanding of "experiments", they often refer to scientific method, commonly used within disciplines such as psychology, chemistry, medicine and sociology. It is a systematic and scientific approach to research in which the researcher manipulates one or more variables, and controls and measures any change in other variables. Within the DRIVER project, experiments mainly relate to the collection of data that feeds into the development of a measure or tool, or any research method that involves the testing of a developed measure or tool.

As the term "experiment" is used broadly within DRIVER and may include a variety of research activities, giving specific recommendations for a general term is difficult. However, based on current understandings of anticipated activities, some advice can be given.

Occasionally the DoW mentions *experimenting through the conduction of workshops and interviews* as a form of experimentation. A workshop where personal data only is collected is not strictly an experiment (more like a dissemination event), and neither is a workshop where individuals contribute with expressing opinions that are recorded, as there is no controlling or manipulation of variables happening. Such workshops will mainly require adherence to the relevant data protection legislation, regarding the collection, storage and processing of (personal) data derived from the workshops (e.g. participation lists or recorded information). Other than that, there are three kinds of experiments foreseen within DRIVER:

1) Experimenting through **table-top** experiments (e.g. in T 52.3). These experiments do also primarily require attention to principles of data protection, although they might differ from workshops as they might request participants to engage in, scenarios and simulated situations- in silico. This could mean that participants don't act out a crisis situation, but enter their (expected) movements into a computer system. Instead of a real life crisis, the situation is steered by a computer system and any movement is registered here and not play-acted. These experiments furthermore require adherence to the general principles for ethical research set out above in 2.3.

2) Experimenting through the **testing** of CM tools (e.g. in 32.4). This is a more hands-on approach to experimenting, as the tools that are being developed will be tested in actual and relevant environments. This will mainly happen within a closed and controlled professional environment. This kind of experimenting usually does not require any additional ethical approvals other than data protection and the adherence to the general principles for ethical research set out above in 2.3.

3) Experimenting through **playing out** a situation, meaning engaging individuals in acting out a real- life scenario according to a number of variables with an unpredictable outcome. It is unsure at this point as to whether this will happen within the scope of DRIVER, and what the likely nature of such experiments would be. This genre of experiments or exercises are regularly conducted by emergency services, and can include e.g. visual effects (such as smoke or fake blood etc.), fully equipped emergency personnel (such as vehicles or weapons) and

volunteers acting out distress or injuries (often with fake injuries or wounds to increase the level of realism). In general, particularly if they are conducted publicly, and could implicate potential physical or mental harms to the individuals involved, this kind of experiments would require ethical follow- up besides the standard data protection and informed consent-routine that implies for the other three kinds of experiments. Although unsure at this point, this is foreseen to be mainly potentially relevant for SP6[6]. Planning activities for SP6 experimentation and demonstration will be analysed accordingly.

> **Recommendation→** If the kind of experiment described in 3) is planned conducted within DRIVER (most relevant for SP6), PRIO should be consulted in advance for ethical consideration, guidelines and approvals.

The experiments within DRIVER mainly happen on the basis of *tactical command & control coordination*. The focus is essentially on the tactical level, and is aimed at testing out the CM tools that are being developed and deployed throughout the project with regard to different needs and questions. This happens in various ways, e.g. through tool-testing followed by an interview with the operator, and other training activities, e.g. for testing a decision-making process tool. Such tactical coordination experiments are to a large extent mainly required to adhere to data protection legislation and the general research ethics principles.

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

- When it comes to experiments foreseen conducted within DRIVER, informed consent (see 3.3.1 for informed consent for experimental research) needs to be collected from all participants.
- In addition to the normal data protection approvals that are most likely needed for collecting data (including experiments), , there is also a possibility that other ethical approvals are needed and that particular guidelines need to be followed, which are set out by national ethics bodies, *if the experiment has traits of the third kind of experiment described*. Such guidelines concern the health, well-being and security of researchers and bystanders subject to the experiments and potential risks related to that. In some countries regulations concerning the health, well-being and security of participants and bystanders are only handled on the level of guidelines; in others the conduction of an experiment requires an actual approval. In most cases the question of approval is dependent on the danger that experiment participants are exposed to, for example when they act out specific situations that can put them in danger, psychologically or physically.

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

National data protection commissioners are authorities with a specific focus on data protection issues, while e.g. university ethics authorities usually have a broader scope. In these cases it is a matter of approaching these bodies to learn about the responsibilities and rules for research ethics for experiments. Often, data protection authorities and other ethical committees are gathered in one authority and may issue both kinds of approvals, but not always. Some institutions have their own ethical advisory boards, such as large companies, universities, labs etc. In Norway, for example, the Norwegian National Committees for Research Ethics (NESH) are independent agencies for questions regarding research ethics, and investigation of misconduct, within all subject areas. NESH mainly focusses on relevant ethical guidelines within different areas that should be followed to ensure good research ethics and "common decency". However, in two cases in particular, approvals are needed, for medical or health research and for research on human remains. We will get back to this in 3.2.1.

3.2.1 Steps to take for obtaining ethical approvals

If needed, obtaining ethical approvals is the responsibility of the individual task leader, and should be sought at the most local level possible. Any task leader conducting experiments thus has to conduct the following steps:

Step 1: The task leader will have to determine **what kind of experiment** will be conducted. That refers to the methodology of the task. If the experiment is de facto a group interview, software testing or a table-top exercise (in silico experimentation), most likely only data protection approvals are needed. Should the experiment involve the acting out of participants, PRIO should be consulted for ethical advice. Most experiments in need of more general ethical approval are also in need of data protection approval.

Step 2: In case the task is in **need of approval** (data protection or other), the task leader will have to identify the most local ethical authority that can issue data protection approvals and potentially other ethical approvals. It is to be investigated whether ethical challenges other than data protection are regulated *via guidelines only* or *via approvals*. If they are regulated via approvals the task leader will have to write an application that sets out the design of the experiment and reflects on how ethical guidelines are being taken care of methodologically.

Step 3: The task leader will have to issue the **appropriate application**, either for data protection approval- in case personal data may be collected, and potentially also for other ethical approvals. In some cases these approvals may be combined[7].

> **Recommendation →** Any experiment conducted in DRIVER should follow the guidelines for ethical research set out in this document and given by local research ethics authorities. Consult PRIO in case you are uncertain about the approval needed for your activity.

[7] Note that also the DRIVER platform providers are Crisis Management professionals that are familiar with executing exercises as well as potential safety and ethical issues and will be able to provide advice as well.

3.2.2 Human Participants

When conducting research on or with human subjects, it is important to minimize harms and risks and maximize benefits. For example, human dignity, privacy, and autonomy needs to be respected, and the research should take special precautions when it deals with vulnerable populations. It should strive to distribute the benefits and burdens of the research fairly, especially when it comes to low income-countries.

When human participants are part of the research, it is possible that additional approvals, relating to additional ethical issues are needed (cf. Experiment of kind 3 described in 3.2). This is only the case when the participants face the chance of being harmed or hurt, either physically or psychologically. Such approvals may be needed if experiments are conducted in public and include volunteers that "act out" reactions and interacting with others. In case any of such actions are planned, please flag them to the DRIVER leadership and the SP9 lead. It may be necessary to obtain medical approvals to ensure that the involved human participants are mentally and physically prepared for the unpredictable nature of the research. This will have to be discussed first.

Other than that, no "research on humans" is foreseen within DRIVER, meaning no experiments on human tissues, cells or the human psyche will be conducted. The project does not collect or work on biological samples or medical/ health related issues. In that case, no ethical approval from *medical* committees is needed. However, in some cases medical committees, data protection authorities and other ethical committees are combined in one body that targets all kinds of research ethical questions.

Should the experimental research have psychosocial effects of some kinds (cf. Experiment of kind 3 described in 3.2), this should be included in the general guidelines for good research ethics. These experiments may need approval from regular ethics committees. These committees also (cf. 3.2) set the conditions for the use of the consent, and may require the project to obtain new consent if the committee deems it necessary. However, for the most part this is not the case in DRIVER. As previously mentioned, the testing of tools and table-top research are the main experimental research taking place. Although these kinds of experiments do not generally require ethical approvals besides protecting the privacy of the human participants, some precautions should be taken (valid for *all* kinds of experiments):

- It is important to identify as exactly as possible, what is being done in the experiments, whether it includes humans, for which purpose and what potential harm they could face.
- When using any human participants, informed consent is crucial.
- If you need participants to play-act, aim at using professional volunteers, meaning pre-organized volunteers from e.g. the Red Cross or THW that have been properly educated and where insurance questions are clarified. Volunteers from these organizations would in addition have the added benefit or value of being aware of some procedures when it comes to handling a crisis during the experimentation, such as first aid. Proper insurance also needs to be in place, to safeguard against potential loss or injury. Should you not be able to use professional volunteers, but civilians, aim to invite civilians organized a sports club or similar, as these are likely to already have the necessary insurance in place through their organization.

- For tool developers and professionals, the requirements for informed consent apply if data is being collected, on the basis of general data protection legislation.

> **Recommendation→** Human participants need both physical and mental safeguards. For participation in experiments aim at professional volunteers or pre-organized civilians, such as sports clubs.

3.3 Key Guidelines for Recruitment of Participants and Data Protection

There are two main aspects of the research process that need to follow specific procedures: The recruitment of participants and the protection of data.

3.3.1 Recruitment of participants and Informed Consent

When it comes to the recruitment of participants for the different research activities within DRIVER, it is important to pay attention to a couple issues to ensure that the collaboration happens lawfully, ethically, and in the best possible way.

One issue has to do with **ensuring diversity** among the participants in the sample. Practically, this means that extra attention needs to be given to creating a balance among the participants regarding gender, age and other demographic variables. This is important to ensure that the outputs of the research (the results) are generalizable and transferrable, and that they reflect a picture of reality that is as accurate as possible.

> **Recommendation →** Ensure diversity among participants in the research (gender, age and other demographic variables).

However, the most central and important issue when it comes to the recruitment of participants has to do with the principle of **informed consent**. Whether the subject a bystander or as an object of research or even a researcher that is not the leader of the task, all individuals have the right to be informed and fully understand the content and extent of the research which they are involved in.

The individual's consent to participate should be based on full information and must be documented, where appropriate, via the collection of individual statements of informed consent. The informed consent forms (for template, see Annex 1) should be collected prior to the research activity, as it forms the very basis of rightful participation in the research. The principle of informed consent plays a particularly crucial role when it comes to conducting experiments. Informed consent means that it

is particularly important to ensure that the participants are well aware of the nature of the experiments, and the purpose of the research.

Failure to properly and fully address issues of informed consent may unnecessarily restrict the usage of data, publishing results and sharing data[8], or may even result in a disapproval of the task by the European commission/project officer (see also D95.21)

Principle rules include that the participants, before taking part in the research, have the right to be informed[9] about the following:

- That participation is voluntary;
- That they may ask questions and receive understandable answers before making a decision about participation;
- The degree of risk and burden involved in participation;
- Who will benefit from participation;
- That they may withdraw themselves and their data from the project at any time;
- How their data will be collected, protected during the project and destroyed at the end.

In addition to the very concept of informed consent, the **quality of the consent** is also an important issue. This has to do with the fact that the consent needs to be given actively by an individual that has had the opportunity to make a real choice, and give real consent. The quality of the consent can pose a problem if the individual participating in the research activity (e.g. the workshop or experiment), is instructed to do so by his or her employer. In this case it is particularly important to make sure that the individual's **right to withdraw** herself and/or her data (the data can be withdrawn up to a certain stage of the research process, usually until the data had been anonymized or encrypted) is clarified.

If you gather video, audio or other visual data (e.g. airborne sensors), the anonymization of data is often impossible. Getting informed consent from the participants is here even more important. Should the individual choose not to participate, it is important to point out that there will be **no consequences** for the individual. In other words, it is very important that the consent needs to be **real** and **actively given.**

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

[8] http://www.data-archive.ac.uk/create-manage/consent-ethics/consent
[9] See Annex 1 for the « Informed Consent Form template » produced in 95.21.

employers is necessary. It is the responsibility of the researcher to be aware of the policy of each organization[10].

To ensure that consent is informed, consent must be given freely with sufficient information provided on all aspects of participation and data use. There must be active communication between the parties. This means that consent must never be inferred from a non-response to a communication, such as a letter[11]. Merely informing the prospective participant about the terms and conditions is not enough. The participant will still have to give consent actively. Further, consent forms must be tailored to the specific research context, stating methods and sample, the nature of the data (personal, sensitive, level of detail), the format of the data (surveys, written, recordings) and the planned data uses and handling. This will influence the type of consent and consent process used[12]. Ask yourself whether informed consent is obtained from the subjects in a reasonable manner and whether it is evident that no dependency relations influence the subject's consent.

You should also give participants the possibility for **"whistle blowing".** Should a project employee develop serious doubts regarding the research ethics of the project, you need to ensure that he or she can be allowed to present his or her worries to an independent consultative body, such as the Ethics Advisory Board. It is furthermore important to make this option known in advance.

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

3.3.2 Data Protection

Compliance with data protection regulations (as well as ethical principles) is a legal requirement. In D95.21, a questionnaire about data protection is provided, which helps the partners perform the first steps in assuring that the research is carried out in conformity with Special Clause 15 of the DRIVER Grant Agreement. Some elaborations on this point are given below. The main ones are:

- Privacy
- Confidentiality
- Storage
- Protection
- Retention
- Ratification
- Destruction

[10] UK Data Archive : *Create & Manage Data- Consent & Ethics, Special Consent.* University of Essex. Available at : http://www.data-archive.ac.uk/create-manage/consent-ethics/consent?index=6

[11] UK Data Archive : *Create & Manage Data- Consent & Ethics.* University of Essex. Available at : http://www.data-archive.ac.uk/create-manage/consent-ethics/consent

[12] Ibid.

Necessary safeguards needs to be taken to protect the **privacy** of individuals, whatever role they play in the research project. This includes the obligation to process data in accordance with individuals' rights. Individuals have (a) a right of access to personal data held about her; (b) a right to prevent the processing of personal data which is likely to cause damage or distress to the individual; (c) a right to prevent the processing of personal data for the purposes of direct marketing; and (d) a right to require that no decision that significantly affects the individual is based solely on automatic processing of personal data[13]. In terms of handling data, it is crucial to ensure **confidentiality** towards both informants and participants. Further, the data needs to be **stored in a correct manner**. For some projects it is a requirement that data is stored for a long time. Make sure that the data is stored securely and proportionally to the purpose, meaning: don't collect too much or insufficient data, or data that does not answer the purpose of your research[14].

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 advice from a specialist. Make sure to use encryption and password protection where necessary. Data should not be stored for a longer time than what is necessary, and it should **eventually be deleted or destroyed.** Annex 2 contains a template for Research Ethics Approval Applications.

In sum, the most central issues regarding **data protection principles** are procedures to ensure and regulate:

Recommendation → Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Process lawfully;
- Make sure to get informed consent;
- Process fairly;
- Collect data only for the purpose specified to the participants;
- Avoid collecting unnecessary data, insufficient data or data that does not answer the purpose of our research
- Don't process data that is not up- to- date;
- Don't keep data longer than necessary;
- Process in accordance with individuals rights;
- Gather, process and store the data securely;
- Use encryption and password protection for collected where necessary
- Make sure not to transfer data outside the EEA- countries.

[13] University of Oxford (2012): *Data Protection and Research*. Legal Services Briefing Note, p .9
[14] Ibid.

4 Safeguards & Principles

4.1 Mitigating Risks

As mentioned before, participants' informed consent is a general and very important rule for all research activities being carried out (cf. 3.3.1).

Personal data gathered during interviews or other research and demonstration activities should be anonymised as soon as possible and stored only as long as necessary. In case personal data is stored after the task for which it has been collected has ended (e.g. for the DRIVER community data base) it should be carefully taken care that it is not being used for any other purpose than the one agreed to by the individual owning the data (which could be called mission creep). Data has to be destroyed as soon as the individual owning the data wants it to be deleted. Task leaders are generally responsible to verify the use of the data and the destruction of it after the project has ended or when the individual participants asks for it.

Personal data gathered for research purpose within the DRIVER project should only be re-used for other purposes after the individual owning the data has been informed about the re-use and agreed to it. Further, it should be thought of any potential mission creep involving the data gathered during the project, i.e. of any potential of using the data beyond the project's benevolent intentions that could violate the privacy of participants (and researchers).

After a research activity that involved human participation has ended, it is important to facilitate de-briefing (cf. also WP23). This is not only to gather additional data and research results, but to enable a full understanding of the situation for all participants and potential expression of disagreement and withdrawal from the project (or informed continuous participation).

Recommendation → Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Anonymize data as soon as possible.
- Destroy data as soon as possible.
- Take care that data is not being used for any other purpose than it has been agreed to be used (mission creep).
- Do not re-use data without written agreement of the owner.
- Make sure that participants in any research activity provide informed consent.
- Facilitate de-briefing for research activity participants.

4.2 Limiting Intrusion

DRIVER research activities may affect also bystanders which were not or could not have been informed about experiments in an easy manner . However, also the protection of personal data and well-being of these bystanders needs to be ensured.

As a general rule, technology for data (or picture) recording, including tracking of location or observation of people should only be used if strictly necessary for the success of the research activity. If not avoidable, measures for minimising intrusion of researchers, participants and bystanders should be installed. In any case, the usage of such technology must be justified.

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

Recommendation →

- Only use technology for data recording, if absolutely necessary. Provide justification.
- Make the conduct of observation or recording of people very clear.
- Give anyone potentially affected by it the possibility to refuse from being observed or recorded.
- Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research.

5 List of DRIVER Recommendations for Ethical Research

Below, a list summarizing all the DRIVER Recommendations for Ethical Research made throughout this document can be found.

- Collect and process data in line with Data Protection Regulations.
- Follow a transparent research process based on neutrality in order to produce valid and accountable research results.
- Have an information plan in place to inform the public, especially prior to public experiments.
- Minimize the potential for dual use.
- Ensure financial equality in research projects.
- Follow research ethics principles of: Transparency, Legality, Validity, Neutrality, Accountability;
- Respect data protection;
- Do not inflict harm on humans and animals, or the environment;
- Respect national law, public and private property (cf. 85.3);
- Implement Privacy and Security by Design wherever possible.
- If the kind of experiment described in 3) is planned conducted within DRIVER (most relevant for SP6), PRIO should be consulted in advance for ethical consideration, guidelines and approvals.
- Any experiment conducted in DRIVER should follow the guidelines for ethical research set out in this document and given by local research ethics authorities. Consult PRIO in case you are uncertain about the approval needed for your activity.
- Human participants need both physical and mental safeguards. For participation in experiments aim at professional volunteers or pre-organized civilians, such as sports clubs.
- Ensure diversity among participants in the research (gender, age and other demographic variables).
- Get *active* and *real* informed consent, inform about the right to withdraw, and facilitate “whistleblowing”.

Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Process lawfully;
- Make sure to get informed consent;
- Process fairly;
- Collect data only for the purpose specified to the participants;
- Avoid collecting unnecessary data, insufficient data or data that does not answer the purpose of our research
- Don't process data that is not up- to- date;
- Don't keep data longer than necessary;
- Process in accordance with individuals rights;
- Gather, process and store the data securely;
- Use encryption and password protection for collected where necessary
- Make sure not to transfer data outside the EEA- countries.

Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Anonymize data as soon as possible.
- Destroy data as soon as possible.
- Take care that data is not being used for any other purpose than it has been agreed to be used (mission creep).
- Do not re-use data without written agreement of the owner.
- Make sure that participants in any research activity provide informed consent.
- Only use technology for data recording, if absolutely necessary. Provide justification.
- Make the conduct of observation or recording of people very clear.
- Give anyone potentially affected by it the possibility to refuse from being observed or recorded.
- Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research.

In addition, follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are as following.

- Anonymize data as soon as possible
- Destroy data as soon as possible.
- Take care that data is not being used for any other purpose than it has been agreed to be used.
- Avoid mission creep.
- Do not re-use data without written agreement of the owner.
- Make sure that participants in any research activity provide informed consent.
- Facilitate de-briefing for research activity participants.
- Process lawfully.
- Make sure to get informed consent.
- Process fairly.
- Collect data only for the purpose specified to the participants.
- Avoid collecting unnecessary data.
- Don’t process data that is not up- to- date.
- Don’t keep data longer than necessary.
- Process in accordance with individuals rights.
- Gather, process and store the data securely.
- Make sure not to transfer data outside the EEA- countries.

6 References

De nasjonale forskningsetiske komiteene (The National Committee for Research Ethics in Science and Technology) (NENT): *Forskningsetisk sjekkliste.* Retrieved Aug 25, 2014 from etikkom.no: http://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Forskningsetisk-sjekkliste/

De nasjonale forskningsetiske komiteene (The National Committee for Research Ethics in Science and Technology) (NENT): *Eksperimenter.* Retrieved Sep 04, 2014 from etikkom.no: https://www.etikkom.no/FBIB/Introduksjon/Metoder-og-tilnarminger/Eksperimenter/

European Commission (2013) Ethics for Researchers. Retrieved Oct 7, 2013 from http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

Norwegian Social Science Data Services (NSD): *Data Protection Official for Research*. Retrieved Aug 25, 2014 from nsd.no: http://www.nsd.uib.no/nsd/english/pvo.html

Oskar Blakstad (Jul 10, 2008). *Experimental Research.* Retrieved Aug 25, 2014 from Explorable.com: https://explorable.com/experimental-research

Oskar Blakstad (Nov 23, 2008). *Ethics in Research.* Retrieved Aug 25, 2014 from Explorable.com: https://explorable.com/ethics-in-research

Resnik, David B. (2011): *What is Ethics in Research & Why is it Important?* National Institute of Environmental Health Sciences. Retrieved Aug 25, 2014 from niehs.nig.gov: http://www.niehs.nih.gov/research/resources/bioethics/whatis/

UK Data Archive : *Create & Manage Data- Consent & Ethics, Special Consent.* University of Essex. Available at : http://www.data-archive.ac.uk/create-manage/consent-ethics/consent?index=6

UK Data Archive : *Create & Manage Data- Consent & Ethics.* University of Essex. Available at : http://www.data-archive.ac.uk/create-manage/consent-ethics/consent

University of Oxford (2012) : *Data Protection and Research.* Legal Services Briefing Note.

7 Annexes

7.1 Informed Consent Form template

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

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

Description of Research

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

DESCRIBE IN 5 SENTENCES:

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

Selection of participants and treatment of data

DESCRIBE IN HALF A PAGE:

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

Your participation

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

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

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

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

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

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

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

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

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

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

Your name in block letters:

Participant's Date & Signature:

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

Kind regards,

(NAME, SIGNATURE LEAD RESEARCHER)

(ADD CONTACT DETAILS OF LEAD RESEARCHER)

7.2 Template for Research Ethics Approval Application

Application for Research Ethics Approval

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

Research conducted within the FP7-funded DRIVER project

« Driving Innovation in Crisis Management for European Resilience »

To be Submitted to ➔ NOTE : FILL OUT RESPONSIBLE INSTITUTION

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

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

General Information

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

Sample

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

Data Collection

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

- Records
- Registers

Data Content

- What is the content of the data?
- Will directly identifying data be collected (social security number, name, date of birth, email, phone number etc.)? Please specify.
- Will indirectly identifying data be collected (it is possible to deduct from background information who the person is likely to be. Background information can be age, gender, part of a specific group etc.). Please specify.
- Will sensitive information about a person be collected? (*"Sensitive personal data* includes any personal data consisting of the following information: race or ethnic origin; political opinions; religious or other beliefs; trade union membership; health; sexuality; or alleged or actual criminality."[15])
- Will information about third persons be collected (secondary information from which it is possible to deduct the identity of a third person)? If so, in what way will the third person be informed?

Informed Consent

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

Information Security

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

Approval by Other Regulating Bodies

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

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

Duration of the Project

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

7.3 Powerpoint presentation

In the following pages, we include a powerpoint presentation summarizing the content of this deliverable. This presentation will be used when communicating the "ethical procedures, risks and safeguards".

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 609043

driver

*Driv*ing Innovation in Crisis Management for *E*uropean *R*esilience

D91.3 ETHICAL PROCEDURES, RISKS AND SAFEGUARDS- SUMMARY

PRIO

What is Research Ethics?

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

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

What it relates to:

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

What role does Research Ethics play and why do we need it?

3

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

General Principles for Ethical Research

4

- When addressing ethical questions, several rules and principles need to be strictly upheld, such as the principles of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data and for the protection of personal data, especially the European Directive 95/46/EC39.

General Recommendations for Ethical Research

5

- Follow a transparent research process based on neutrality in order to produce valid and accountable research results.
- Have an information plan in place to inform the public, especially prior to public experiments.
- Ensure financial equality in research projects.
- Implement Privacy and Security by Design wherever possible.
- Respect data protection;
- Do not inflict harm on humans and animals, or the environment;
- Respect national law, public and private property (cf. 85.3);
- Inform the public;
- Minimize dual use;
- Provide equal shares of the finances.

Experiments in DRIVER

6

All DRIVER Experiments need to follow Research Ethics.

But what exactly do the DRIVER experiments do?

- Occasionally the DoW mentions *experimenting through the conduction of workshops and interviews* as a form of experimentation. A workshop where personal data only is collected is not strictly an experiment (more like a dissemination event), and neither is a workshop where individuals contribute with expressing opinions that are recorded, as there is no controlling or manipulation of variables happening. Such workshops will mainly require adherence to the relevant data protection legislation, regarding the collection, storage and processing of (personal) data derived from the workshops (e.g. participation lists or recorded information). Other than that, there are three kinds of experiments foreseen within DRIVER.

Three kinds of DRIVER experiments

7

1. Experimenting through **table-top** experiments (e.g. in T52.3).

These experiments primarily require attention to principles of data protection, although they might differ from e.g. workshops as such experiments might request participants to engage in scenarios and simulated situations- in silico. This could mean that participants don't act out a crisis situation, but enter their (expected) movements into a computer system. Instead of a real life crisis, the situation is acted out in a virtual environment steered by a computer system and any movement is registered here and not play-acted. These experiments furthermore require adherence to the general principles for ethical research set out in previous slides.

Three kinds of DRIVER experiments

8

2. Experimenting through the **testing** of CM tools (e.g. in 32.4).

This is a more hands-on approach to experimenting, as the tools that are being developed will be tested in actual and relevant environments. This will mainly happen within a closed and controlled professional environment. This kind of experimenting usually does not require any additional ethical approvals other than data protection and the adherence to the general principles for ethical research set out in previous slides.

Three kinds of DRIVER experiments

9

3. Experimenting through **playing out** a situation (potentially in SP6?).

This means engaging individuals in acting out a real- life scenario according to a number of variables with an unpredictable outcome. This genre of experiments or exercises are regularly conducted by emergency services, and can include e.g. visual effects (such as smoke or fake blood etc.), fully equipped emergency personnel (such as vehicles or weapons) and volunteers acting out distress or injuries (often with fake injuries or wounds to increase the level of realism). In general, particularly if they are conducted publicly, and could implicate potential physical or mental harms to the individuals involved, this kind of experiments would require ethical follow- up beyond the abovementioned. It is unsure if and how this will happen within the scope of DRIVER, but planning activities for SP6 experimentation and demonstration will be analysed accordingly.

Experiments and Research Ethics

10

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

- When it comes to experiments foreseen conducted within DRIVER, informed consent needs to be collected from all participants.
- Data protection approvals are most likely needed for most DRIVER experiments.
- Other ethical approvals may be needed, if the experiment has traits of the third kind of experiment described. Such guidelines concern the health, well-being and security of researchers and bystanders subject to the experiments and potential risks related to that. In some countries regulations concerning the health, well-being and security of participants and bystanders are only handled on the level of guidelines; in others the conduction of an experiment requires an actual approval. In most cases the question of approval is dependent on the danger that experiment participants are exposed to, for example when they act out specific situations that can put them in danger, psychologically or physically. **Consult PRIO if you plan an experiment of the third type.**

Experiments & the Collection of Personal Data

11

What is personal data?

- Information does not have to be factually correct in order to be personal data.
- A person's identity can be obtained in different ways:

- *directly* from identifiers such as names, addresses, postcode information, telephone numbers or pictures,
- *indirectly* from identifiers which, when linked with other publicly available information sources, e.g. information about workplace, occupation or characteristics like salary or age.

Main Data Protection Principles

12

Compliance with data protection regulations (as well as ethical principles) is a legal requirement.

Main Data Protection points of attention :

- Privacy
- Confidentiality
- Storage
- Protection
- Retention
- Ratification
- Destruction

Specific Recommendations for Ethical Research: Data Protection

13

Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Process lawfully;
- Make sure to get informed consent;
- Process fairly;
- Collect data only for the purpose specified to the participants;
- Avoid collecting unnecessary data, insufficient data or data that does not answer the purpose of our research;
- Don't process data that is not up- to- date;
- Don't keep data longer than necessary;
- Process in accordance with individuals rights;
- Gather, process and store the data securely;
- Use encryption and password protection for collected where necessary;
- Make sure not to transfer data outside the EEA- countries.

Experiments and Human Participants

14

- It is important to identify as exactly as possible, what is being done in the experiments, whether it includes humans, for which purpose and what potential harm they could face.
- When using any human participants, informed consent is crucial.
- If you need participants to play-act (third kind of experiment mentioned), aim at using professional volunteers, meaning pre-organized volunteers from e.g. the Red Cross or THW that have been properly educated and where insurance questions are clarified. Volunteers from these organizations would in addition have the added benefit or value of being aware of some procedures when it comes to handling a crisis during the experimentation, such as first aid.
- Proper insurance also needs to be in place, to safeguard against potential loss or injury. Should you not be able to use professional volunteers, but civilians, aim to invite civilians organized a sports club or similar, as these are likely to already have the necessary insurance in place through their organization.
- For tool developers and professionals, the requirements for informed consent apply if data is being collected, on the basis of general data protection legislation.

Specific Recommendations for Ethical Research: Human Participants

15

- Human participants need both physical and mental safeguards. For participation in experiments aim at professional volunteers or pre-organized civilians, such as sports clubs.
- Ensure diversity among participants in the research (gender, age and other demographic variables).
- Get *active* and *real* informed consent, inform about the right to withdraw, and facilitate "whistleblowing".

Specific Recommendations for Ethical Research: Recruitment of Participants

16

Principle rules include that the participants, before taking part in the research, have the right to be informed about the following:

- That participation is voluntary;
- That they may ask questions and receive understandable answers before making a decision about participation;
- The degree of risk and burden involved in participation;
- Who will benefit from participation;
- That they may withdraw themselves and their data from the project at any time;
- How their data will be collected, protected during the project and destroyed at the end.

Mitigate Risks

17

Follow the relevant data protection principles. Key duties, as stated and elaborated in Chapter 6 of D95.21 are:

- Anonymize data as soon as possible.
- Destroy data as soon as possible.
- Take care that data is not being used for any other purpose than it has been agreed to be used (mission creep).
- Do not re-use data without written agreement of the owner.
- Make sure that participants in any research activity provide informed consent.
- Facilitate de-briefing for research activity participants.

Limit Intrusion

18

- Only use technology for data recording, if absolutely necessary. Provide justification.
- Make the conduct of observation or recording of people very clear.
- Give anyone potentially affected by it the possibility to refuse from being observed or recorded.
- Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research.

Obtaining Ethical Approvals

19

Three- step approach:

- **Step 1:** The task leader will have to determine **what kind of experiment** will be conducted. That refers to the methodology of the task. If the experiment is de facto a group interview, software testing or a table-top exercise, most likely only data protection approvals are needed. Should the experiment involve the acting out of participants, PRIO should be consulted for ethical advice. Most experiments in need of more general ethical approval are also in need of data protection approval.
- **Step 2:** In case the task is in **need of approval** (data protection or other), the task leader will have to identify the most local ethical authority that can issue data protection approvals and potentially other ethical approvals. It is to be investigated whether ethical challenges other than data protection are regulated via guidelines only or via approvals. If they are regulated via approvals the task leader will have to write an application that sets out the design of the experiment and reflects on how ethical guidelines are being taken care of methodologically. *The task leader will report the respective task to PRIO.*
- **Step 3:** The task leader will have to issue the **appropriate application**, either for data protection approval- in case personal data may be collected, and potentially also for other ethical approvals. In some cases these approvals may be combined. *The approved application will have to be sent to PRIO in good time before the research starts.*

Final Remarks

20

- The contents of this presentation are discussed in D91.3 and D95.21 in detail.
- D95.21 includes a calendar for expected approvals and all D95.2x include updated lists of tasks that need approvals in the next round.
- D91.3 includes templates for informed consent forms and data protections approval applications.