RESEARCH ETHICS COMPLIANCE KIT

J. PETER BURGESS
Oslo Centre for Science in Society (Norway)

TRAINING AUGMENTED REALITY GENERALISED ENVIRONMENT TOOLKIT

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 653350.

Work programme FCT-7-2014: "Law enforcement capabilities topic 3: Pan European platform for serious gaming and training"

Submission date: 29 October 2015

© TARGET Consortium 2015

RESEARCH ETHICS COMPLIANCE KIT

DELIVERABLE 8.03

EXECUTIVE SUMMARY

The deliverable sets out the basic principles and responsibilities that flow from European Commission regulations on research ethics. It describes the ethics review process and gives general guidelines on where responsibilities lie and how they can be fulfilled. It describes concrete procedures for assessing the need for ethics issue mitigation and provides tools for the practical work of managing ethics issues on the task level.

INTRODUCTION

Research ethics as it is practiced in all Horizon 2020 research activities grows primarily out of the medical sciences, but has come to be applicable to all fields for research, in particular the social sciences.

Historically, the political importance and practical visibility of research ethics can be traced to the Nuremberg Code, which set the standard for the legitimacy and credibility of research ethics. The code, which has never been codified in law, was the first formulate in Nuremberg in the wake of the famous Nuremberg trials that judged countless Nazis for their participation in war crimes. Among those tried, as perpetrators of crimes against humanity were doctors of the Nazi regime who were accused of carrying out scientific experiments on detainees against their will.

Although the Nuremberg Code consists of 10 rules, those most relevant for socially-oriented research are 4 in number: ***consent*** (that objects of research experiments have the right to understand and consent to the procedure to be carried out on them; ***proportionality*** (that the scientific intervention does not imply procedures or experiences more invasive than absolutely necessary to obtain the experimental results sought after); ***necessity*** (that the procedure is absolutely indispensable in order to obtain the results sought after); and ***the right to withdraw*** (that the object may terminate the procedure freely and at any time).

In the context of European Union research funding, the Nuremburg Code has been taken very seriously and explicitly linked to European traditions of human rights. Its principles are deeply enshrined in the EU treaties. They were given additional force by the adoption of the European Charter of Fundamental Rights, itself integrated into the Treaty of the European Union.

MAIN SECTION

CORE DOCUMENTS

Legal foundation

In the **EU Regulation** passed by the European Parliament, **Establishing the Horizon 2020**, Article **19** ('Ethical principles') sets out that:

All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supple-mentary Protocols.

Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

Ethics review

Article 14 of the **Grant Agreement** describes the conditions under which and ethics review should take place:

1. The Commission shall systematically carry out ethics reviews for proposals raising ethical issues. That review shall verify the respect of ethical principles and legislation and, in the case of research carried out outside the Union, that the same research would have been allowed in a Member State.

2. The Commission shall make the process of the ethics review as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, the resub-mission of documents.

The primary obligation to comply with principles of ethics in all Horizon 2020 projects is enshrined in the **Article 34** of the Grant Agreement

34.1 Obligation to comply with ethical principles: The beneficiaries must carry out the action in compliance with:

(a) Ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and (b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) Aim at human cloning for reproductive purposes; (b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or (c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues: Activities raising ethical issues must comply with the 'ethics requirements' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit to the Commission copy of:

(a) Any ethics committee opinion required under national law and (b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

RESEARCH ETHICS: THE BASIC PRINCIPLES

'Do no harm'

Research ethics is for the most part straightforward, even common sense. Most researchers - and indeed all the researchers in the TARGET consortium - are committed to holding the highest ethical standards for doing research.

In the simple terms, research ethics, involves two general ideas: (1) the research should do no harm, either physical or non-physical and (2) that participation in research should be voluntary.

To 'do no harm' can be differentiated along several lines.

The rule of 'do no harm' applies to several groups. It applies first and foremost to those individuals (human or animal) that are the **objects of research**, in other words, that are being studied in one way or another. It also applies to **researchers** themselves who may be involved in hazardous or troublesome activities in carrying out the research. Furthermore, research activities can implicate a variety of **bystanders** either involved or uninvolved in the research. All of these types of participants have the right to protection.

Finally, it is important to recall that implicated individuals can be implicated without knowing it. Or they can be involved in full knowledge but without full consent. To deal with both of these cases, there needs to be an informed consent procedure in place. We return to this below.

Physical harm. It goes without saying that no physical or psychological harm should result from the research being carried out. However guarding against to the fullest requires reflection and careful planning. Physical and psychological harm can involve several different groups that find themselves implicated by our research. If research is done on other human beings, either through physical intervention, observation, or information gathering, then these individual should be protect from bodily harm and psychological duress. Indeed they have a right to it.

Psychological harm. Research can inflict, both willingly or unwilling—psychological hardship on researchers, research objects or on different types of bystanders.

Moral harm. By 'moral harm' we mean harm to one's dignity. This means harm to one's feeling of autonomy, worthiness, identity or sense of moral self. Degrading procedures, humiliation, either direct or indirect, fall

under this category. However, the most common expression of the right to protections of this kind falls under **privacy and data protection**. Whereby intrusions into an individual's private sphere is deemed to be a morally harmful event. We return to this below.

Harm to the environment. Research should not have any detrimental effects on the environment, either as a consequence of the research procedure or in short- or long-term aftermath of the procedure.

Harm to property. Research should not damage or compromise private property, either as a primary intended consequence of the research, as an unintended consequence of the research, or as an unknown, unintended secondary consequence of the research. Responsibility for such damage falls to the person responsible for the activity.

Integrity and dignity of persons

Research should not do anything to endanger, even potentially, the dignity of human beings, both those participating in the scientific exercise or those who are not. This means that the value of human beings in themselves, in contrast to the value that can be produced by using humans as a means to something greater. Human subjects should not be used to obtain something that is regarded as of higher value than they are.

Privacy and personal data protection

Individual research subjects have an absolute right to privacy and to the protection of their own personal data. Personal data may be defined as any data permitting to identify the person involved. Data that human subjects give to a research collection will be treated such that it is not accessible to anyone other than the individual and the researcher involved.

Informed consent

Individuals research subjects should be fully informed about all aspects of the research in which they are being asked to participate, including the future use of the data they might provide, the complete details and possible dangers they might face.

Proportionality

As noted above, the research should not imply procedures or experiences more invasive than necessary or requiring the human subject to go beyond stated objectives (mission creep).

Transparency and integrity

The research treats societal concerns seriously maintaining awareness of the public and its concerns, reacting to the public.

Dual use

The research should avoid making research procedures and results exposed to misuse or malignant dual use by terrorists or military organisations.

ETHICS REVIEW PROCEDURES

Horizon 2020 foresees 3 levels of ethics review, in increasing degree of severity and rigour: ethics self-assessment, ethics review, and ethics audit. The application of these different levels is determined by the results of the previous, inferior level.

4.1 Ethics self-assessment

For all proposals to Horizon 2020, an Ethics Issues Table (EIT) must be completed as part of the application procedure. If at least one issue is signalled, the applicants must:

i) Describe how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues will be performed;

ii) Provide a copy of any already obtained ethics committee opinion, required notification or authorisation;

iii) Describe in detail how the ethics issues identified in the Ethics Issues Table will be addressed in particular in relation to:

- the research objectives per se (e.g. study of vulnerable populations, dual use, etc.)

- the research methodology (e.g. experiments or trials, involvement of children and related consent procedures, protection of data collected etc.)

- the potential impact of the research (e.g. questions related to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use, etc.).

Ethics review (before the finalisation of GA)

Ethics screening

All proposals that are assessed above the scoring threshold and potentially considered for funding are submitted to ***ethics screening***. The screening begins with an ***ethics pre-screening*** involving a minimum of two ethics experts and taking into account the proposal-level self-assessment. The objective of the pre-screening is to identify potential ethical issues but not to assess them. Proposals with at least one confirmed ethical issue will be subject to the full ***ethics screening***. The ***ethics screening*** is carried out during the scientific evaluation or soon after. Each proposal is screened by at least two independent ethics experts (they can be the same experts who performed the pre-screening)

There are 4 possible outcomes of this screening:

1. The proposal is judged to be 'ethics-ready' and the grant agreement may be finalised;
2. The proposal is given conditional clearance, whereby experts formulate requirements, which will become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the grant preparation can be finalised.
3. The proposal is referred to a full ***ethics assessment***. This concerns a limited number of proposals with complex ethical issues (e.g. severe intervention on humans, etc.) The screening panel can recommend an ***ethics assessment*** prior to the signature of the grant agreement and, if appropriate, list the additional information to be provided;
4. The proposal is denied an ethics clearance.

Ethics assessment

A full ethics assessment is an in-depth analysis of the ethical issues of the issues flagged by the ethics screening experts. A panel consisting of at least 5 independent ethics experts carries it out. It takes into account, when available, the analysis done by during the ethics screening as well as the information provided by the applicants in response to the ethics screening. The possible outcomes of the ethics assessment are:

1. The applicants are found to have provided the necessary elements such that the grant agreement can be finalised;
2. The experts formulate new requirements, some to be fulfilled before the signature of grant agreement, others becoming contractual obligations and annexed to the grant agreement. The experts may also recommend an ***ethics check*** and indicate an appropriate timing for the check.
3. The experts consider that the elements submitted are not sufficient and request a second ethics assessment, indicating the weaknesses to be addressed and the information to be provided. In this case, the signature of the grant agreement is postponed until the results of the second ethics assessment.

Ethics check and audit

Based on the conclusions of the ***ethics review*** at the initiative of the ethics expert group, an ethics check can be undertaken. The objective of the ***ethics check*** is:

- To assist the beneficiaries in dealing with the ethics issues raised by their research and, if necessary,
- To take preventive or/and corrective measures primarily on the basis of the requirements of the **Ethics Review Reports** and, when available, the reports of the Ethics Advisor or Ethics Board. Whenever appropriate the concerned beneficiaries may be invited to a meeting with the European Commission to discuss the issues at stake. On-site visits can also be organised. The ***ethics check*** may also address issues related to breaches of research integrity, in particular scientific misconduct. In the case of substantial breach of ethical principles, research integrity, or relevant legislation an ***ethics audit*** can be undertaken. The procedure is foreseen in the grant agreement (Article 22). These ethics checks and audits can result in an amendment of the grant agreement. In severe cases, it can lead to a reduction of the grant, its termination or any other appropriate measures, in accordance with the provisions of the grant agreement.

RESEARCH ETHICS ISSUES POTENTIAL RELEVANT FOR TARGET

Research conducted in the TARGET project will likely engages research ethics along two lines:

Data protection and privacy issues with collection of project specifications from end-users not a part of the

consortium, information gathering, and/or feedback and self-assessments carried out in focus groups or workshops. It also potentially covers visual data collected through the drone surveys of WP4. At this early stage in the project, this implicates the following tasks:

Task 1.3 TNA workshops at each practitioner-user site

Task 1.5 Training designers & training managers' workshop

Task 1.6 Coordinate and deliver user trials at each practitioner-user trial site

Task 4.3 Photogrammetry Survey Drone

Safety and well-being issues connect with testing and training exercises that could have physical or psychological impact on consortium members or non-consortium members. At this early stage in the project, this implicates the following tasks:

Task 5.5 Interaction Prototyping and Testing

Task 5.7 Test Scenarios

Task 6.5 Training content 1 Task 6.5 TC1 Training of commanders at strategic level on large scale actions

Task 6.6 Training content 2 Task 6.6 TC2 Protecting a critical infrastructure and dealing with crowds during a mass demonstration

Task 6.7 Training content 3 Task 6.7 TC3 Response to a massive cyber-attack on the infrastructure of an energy grid.

Task 6.8 Training content 4 Task 6.8 TC4 Tactical firearms vignettes (snipers; multiple agents cooperating).

Task 6.9 Training content 5 Task 6.9 TC5 Road Traffic event involving Casualties and Driver with Offensive Weapon (Field-based).

Task 6.10 Training content Task 6.10 TC5 Road Traffic event involving Casualties and Driver with Offensive Weapon (Field-based).

These lists should be revised as the project matures, new needs are identified and modifications are made.

PRACTICAL PROCEDURE FOR GETTING STARTED WITH RESEARCH ETHICS MANAGEMENT

A simple procedure for self-assessing research tasks in collaboration with the Ethics Manager is the main course for mitigating risks stemming from the European standards for research ethics.

Research ethics are applicable at the task level. The task leader is responsible for assuring the ethical consistency of all activities associated with the task. A task-by-task assessment should be made in good time. Ethical issues can in some cases be collectivised across several similar tasks. This should be done in consultation with the Ethics Manager.

Each tasks can be assessed by using a simple **Ethics self-assessment** method, presented as Annex 1.

If ethics mitigation is judged necessary, an **Ethics issue memo** should be generated either directly in the

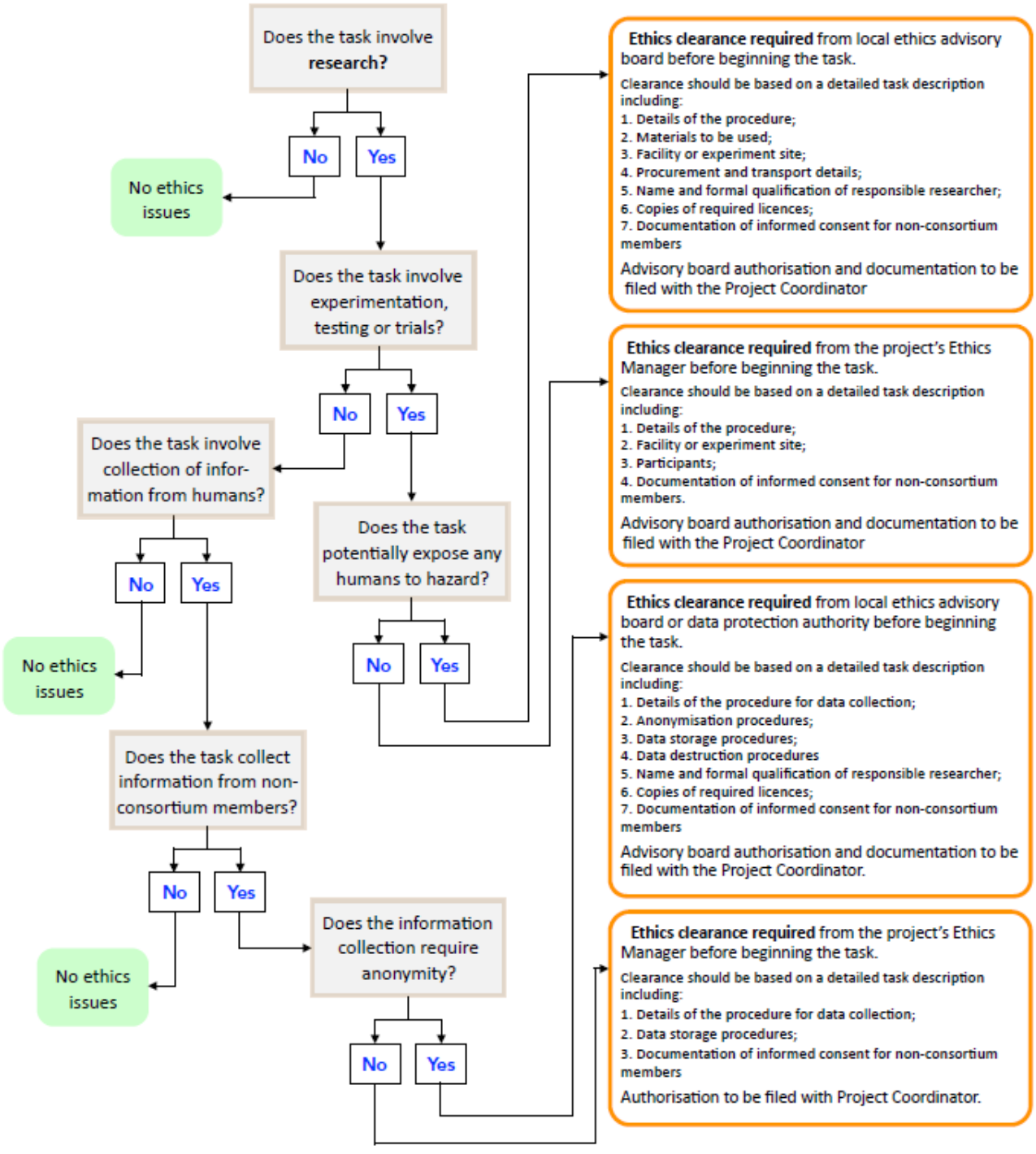
template attached in Annex 2, or by passing the relevant information to the Ethics Manager. The memo will be integrated into a project ethics issue database and a copy provided to the Project Office. The memo can and should be revised as more information becomes available.

For the purpose of documenting informed consent, there are two informed consent templates in the annex. The first one is for data collection exercises; the second is for activities where physical or psychological harm might be involved.

In cases where ethics approvals are required, these should be sought at the most local level possible. The Network of European Research Ethics Committees (EREC) keeps a list over national ethics committees (http://www.eurecnet.org/information/index.html), though this is often only the first stop. For questions of privacy and data protection, the European Commission maintains a list of national data protection agencies (http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm)

In all cases, the relevant documents should be on file with the Project Office, and uploaded on the dedicated area of the project's online workshop, and copied to the Ethics Manager.

ANNEX 1: ETHICS SELF-ASSESSMENT



© TARGET Consortium 2015

ANNEX 2: ETHICS ISSUE MEMO TEMPLATE

Exercise date:	
Workpackage:	
Task:	
Responsible partner:	
Contact:	
Task description:	
Site:	
Ethics issue:	
Proposed mitigation:	
Authorising body:	

ANNEX 3: MODEL INFORMED CONSENT FORMS FOR TARGET DATA COLLECTION

DECLARATION OF INFORMED CONSENT: DATA COLLECTION

About the project

The primary aim of the TARGET project is to design and develop a pan-European platform for hybrid serious gaming, including training content development tools, providing standard interfaces and effective mechanisms for integrating third-party technologies and content, and supporting content and technology sharing, licensing and payment. In order to see this aim it deliver a set of TARGET technology components (virtual reality, competence assessment, decision support, non-linear simulation...) by respectively adapting and improving existing as well as developing dedicated new components fitting into the TARGET platform. Moreover, the project develops a range of six dedicated training contents for a broad range of needs, responding to specific major identified issues as well as assess and trial the TARGET Platform. Finally, it will carry out trials and assessments of the training platform and the training contents, in dedicated sessions including single end-user, team and transnational sessions, and to develop best practices

Duration, funding and partners

The TARGET project is funded by the European Commission under Horizon 2020, running from 01 May 2015 to 30 April 2017, with an overall budget of approximately € 6 million. The project gathers partners from 9 European countries, and from all areas of security research, with a strong emphasis on end-users. The research procedures in which you are involved will be carried out _____ at _____ under the responsibility of lead-researcher _____

Purpose of the data collection in which you are involved

The aim of collecting information is to learn more about the needs of users of serious-gaming in a variety of applications and settings, with a range of end-users, and with widely differing specifications. The data you provide will _____

Data collection and storage

_____

Anonymity

_____

Refusal or cessation of participation

Participation in this study is voluntary. You do not have to participate in the study if you do not want to. If you choose to participate, you can nonetheless chose to withdraw or leave the study at any time without consequences for you and without being required to provide any explanations.

Additional information may be obtained by contacting TARGET project office at target-arttic@eurtd.com.

I hereby consent:

Name: _____

Organization: _____

Date: _____

Signature: _____

ANNEX 4: MODEL INFORMED CONSENT FORMS FOR TARGET TRAINING AND TESTING

DECLARATION OF INFORMED CONSENT: DATA COLLECTION

About the project

The primary aim of the TARGET project is to design and develop a pan-European platform for hybrid serious gaming, including training content development tools, providing standard interfaces and effective mechanisms for integrating third-party technologies and content, and supporting content and technology sharing, licensing and payment. In order to see this aim it deliver a set of TARGET technology components (virtual reality, competence assessment, decision support, non-linear simulation...) by respectively adapting and improving existing as well as developing dedicated new components fitting into the TARGET platform. Moreover, the project develops a range of six dedicated training contents for a broad range of needs, responding to specific major identified issues as well as assess and trial the TARGET Platform. Finally, it will carry out trials and assessments of the training platform and the training contents, in dedicated sessions including single end-user, team and transnational sessions, and to develop best practices

Duration, funding and partners

The TARGET project is funded by the European Commission under Horizon 2020, running from 01 May 2015 to 30 April 2017, with an overall budget of approximately € 6 million. The project gathers partners from 9 European countries, and from all areas of security research, with a strong emphasis on end-users. The research procedures in which you are involved will be carried out _____ at _____ under the responsibility of lead-researcher _____

Purpose of the data collection in which you are involved

The aim of collecting information is to learn more about the needs of users of serious-gaming in a variety of applications and settings, with a range of end-users, and with widely differing specifications. The data you provide will _____

Data collection and storage

_____

Anonymity

_____

Refusal or cessation of participation

Participation in this study is voluntary. You do not have to participate in the study if you do not want to. If you choose to participate, you can nonetheless chose to withdraw or leave the study at any time without consequences for you and without being required to provide any explanations.

Additional information may be obtained by contacting TARGET project office at target-arttic@eurtd.com.

I hereby consent:

Name: _____

Organization: _____

Date: _____

Signature: _____

© TARGET Consortium 2015

GLOSSARY

Abbreviation / Acronym	Meaning
EIT	Ethics Issues Table
EREC	Network of European Research Ethics Committees
EU	European Union
GA	General Assembly
TC	Training case
TNA	Training needs analysis