D1.8 INFORMED CONSENT PROCEDURES AND RECRUITMENT CRITERIA

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Executive summary

Deliverable D1.8, Informed consent procedures and recruitment criteria, defines key ethical issues concerning research activities, as identified and established according to EU and national directives. These issues are examined from the Project point of view and include recruitment of participants, information to participants, informed consent and data handling during the planned research activities.

After its formal release, updated versions will be possible.

Revision history			
Version	**Date**	**Created / modified by**	**Comments**
0.0	23/03/15	Massimilano Bromuri	First, incomplete draft, for MO internal circulation.
0.1	24/03/15	Luca Mari	Extensions, fixes, etc. First distribution to SB.
0.2	26/03/15	Luca Mari	Extensions, fixes, etc.
0.3	29/03/15	Luca Mari	Extensions.
1.0	31/03/15	Luca Mari	Fixes after comments by SB members. Approved version, submitted to the EC Participant Portal.

Table of Contents

1. Introduction

1.1 Purpose of the informed consent procedures and recruitment criteria

Key ethical issues concerning research activities are identified and defined here according to EU and national directives. These issues are examined from the Project point of view and include recruitment of participants, information to participants, informed consent and data handling during the planned research activities.

1.2 Application area

The procedures and criteria specified in this document shall be applied:

- by all partners,
- for all procedures of data acquisition involving subjects external to the Project Consortium ("participants" henceforth) in a non-anonymous form.

Each partner supervises and checks the work performed by its own staff in accordance with this document.

This document is to be interpreted with reference to:

- the Grant Agreement (GA);
- the Consortium Agreement (CA).

1.3 Document evolution procedure

Different events may cause the content of this document to be modified, for example:

- changes of project characteristics;
- changes in techniques or tools.

Any partner may request changes, but each change must be analysed by the Project Steering Board (SB).

1.4 Terms and acronyms

EC	European Commission
REA	Research Executive Agency
GA	Grant Agreement
CA	Consortium Agreement
SB	Steering Board
WP	Work Package
MO	Management Office

2. Informed consent procedures

The consent procedure is an important aspects to participate in an investigative activity. Before requesting consent, the investigator shall make sure that the potential participant, or her/his legal

representative, has received written, and if desirable oral, information. This information should be provided in such a way that it is probable that the potential participant, or her/his legal representative, understands the contents. Furthermore, s/he should be given sufficient time to make a proper decision on the requested consent.

Participants shall be informed that they are free to withdraw from participation at any point, that their personal data will remain confidential and anonymous, and that collected data will be analysed for the entire group of participants, rather than individually, thus securing their privacy and anonymity.

For investigations involving minors, the information will be provided to them and their parents/authorized adult using a language that is comprehensible and suitable for each group. The information should be clear and adequate in order for the minor to make decision about participation.

Detailed information shall be provided to the potential participants by means of an information sheet including descriptions / specifications of:

- purpose of the research;
- duration of the research activities;
- adopted procedures;
- voluntary participation;
- possible risks, discomfort or disadvantages;
- benefits to the subject or others;
- data protection and confidentiality and privacy policies;
- where to get more information;
- what happens to data, samples and results at the end of the research.

A sample informed consent document, including this information sheet, is provided in Annex 1. In order to make it more efficiently usable in investigation activities, the document shall be downloadable from the Project website, possibly in translated versions for activities involving non-English native speakers.

In the case the investigative activity is performed in a context organized by an institution external to the Project (e.g., a school), and such an institution operates its own informed consent procedure, this procedure shall be considered sufficient also to the purposes of the Project upon verification of its conformity to the present specifications.

3. Recruitments criteria

For each investigation activity details on the procedures and criteria that will be used to identify/ recruit participants shall be provided. It is at the participant’s discretion as to whether s/he wishes to participate in the investigation activity or not.

Researchers contact details will be provided, for participants to contact the Project Consortium for information and decide whether they wish to join in.

4. Ethics requirements

The Project activities will be carried out with regard to ethical implications and respecting the regulations expressed in international texts and codes of practices, in particular the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The activities should not entail any risk and burden for the individuals concerned. All the experimental data shall be collected and used in respect of the European Parliament's directive and legislations.

Expected tools for data acquisition will consist of surveys, questionnaires, interviews and focus groups. Data acquisition will be performed in particular in the context of WP3, "Analysing how DiDIY is reshaping organization and work", WP4, "Analysing how DiDIY is reshaping education and research", and WP5, "Exploring the impact of DiDIY on creative society". Involved persons will be properly informed of the Project aims, expected results and limits of the research in the information supplied before getting the informed consent.

An external independent Ethics Advisor is appointed to oversee the ethical concerns involved in this research: Dr. Paolo Della Vedova (Italian Court of Cassation lawyer, legal adviser for several companies, university researcher on Laws of civil procedure, legal adviser to the Consul General of the Republic of Costa Rica in Milan in the period 1993–96; Law Office "Della Vedova, Maggi & Partners", Via Sempione 8 Bis, 21052 Busto Arsizio, Italy; CF PI: 03384430124). A report by the Ethics Advisor shall be submitted to the EC REA with the financial reports [GA – 1.4 Ethics Requirements].

Due to the nature of the investigation activities to be performed, ethically relevant incidental findings are not expected. In case of actual incidental findings [GA – 1.4 Ethics Requirements], details shall be collected and provided to the Ethics Advisor.

In case of other ethics issues, copies of ethical approvals by the competent authorities shall be submitted to the EC REA [GA – 1.4 Ethics Requirements].

5. Data protection

The general principles are:

- detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation [GA – 1.4 Ethics Requirements];
- justification must be given in case of collection and/or processing of personal sensitive data [GA – 1.4 Ethics Requirements].

European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data shall be taken into account for the main guidelines, as related to the:

- quality of data and data processing;
- legitimacy and categories of data processing;
- right of access to the personal data;
- subject's right of information and objection;

- confidentiality and security of processing

(the full text of the Directive and a short summary can be found on the official website of the European Union).

In compliance with to such Directive, Article 8, no data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, healthy and sex life shall be processed. Only data with a strict connection with the aim of the research will be collected. Data will be anonymised at the acquisition time and will be managed by the researchers involved in the Project by means of a numerical identifier. The "right to be forgotten" Directive will be fully satisfied, and collected data will be destroyed at the end of the Project.

The Project shall not involve activities or results raising security issues, nor "EU-classified information" as background or results [GA – 2.3.6.2 Security].

Personal data will be properly managed by the Coordinator Data Protection Officer, namely the General Director of LIUC, Dr. Massimo Colli [GA – 2.3.6.1 Ethics].

In the case the investigation activity does not directly involve the Coordinator, the investigator shall appoint an ad hoc Data Protection Officer in its own institution, who will transfer all information on acquired personal data to the Coordinator Data Protection Officer after the completion of the investigation activity.

5.1 Data protection plan

The protection of the privacy of participants is a responsibility of all persons involved in research with human participants. Privacy means that each participant can control the access to personal information and is able to decide who has access to the collected data in the future.

Due to the principle of autonomy, the participants have to be asked for their agreement (see Annex 1) before private and personal information is collected. It shall be ensured that all persons involved in research studies understand and respect the requirement for confidentiality. The participants shall be informed about the confidentiality policy that is used in this Project.

The Project shall adhere to strict anonymisation policy: in order to protect the participants privacy and anonymity, each participant will be given a unique user code, and all collected data will be associated with this code.

Collected data will be saved on secured servers, and will not be available to anyone outside the Project's team.

In case that data of specific participants is used for illustration in scientific publications or demonstrations, additional consent of the respective individuals will be required. This consent can be revoked at any time and the right to revoke consent will be expressed to participants when entering the study.

Annex 1: Sample informed consent document

Informed Consent

Project Acronym:	DiDIY
Project Name	Digital Do It Yourself
Grant Agreement no.	644344
Start date of the project	01/01/2015
End date of the project	30/06/2017
Financed by	EU
Programme	H2020-ICT-2014-1
Website	www.didiy.eu

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1. INTRODUCTION

You have been invited to take part in a research study. Before making a decision on whether you want to participate or not, please read this document carefully. Please ask all the questions you may have so you can be completely sure to understand all the proceedings of the study, including risks and benefits.

This informed consent document may include words that you do not understand. If this is the case, please ask the contact researcher or any other member of the study to fully explain the meaning of the word or piece of information you do not accurately understand. At all times, we assure the compliance with the current legislation.

2. PURPOSE OF THE STUDY/PROJECT

The Project aims at:

- setting a conceptual framework to explore the impact of the phenomenon of digital do it yourself, "DiDIY" for short;
- producing information, models and guidelines to support education and policy making on DiDIY that, while enabled by technology, should be driven by social and cultural strategies.

Summary of the Project

Digital do it yourself (DiDIY) is a new socio-technological phenomenon in which the widespread availability of digital devices supporting the convergence of physical and informational components and the growing accessibility of knowledge and data through open online communities presage scenarios in which the distinction between users and producers of physical artefacts is fuzzy and

new opportunities and threats emerge. DiDIY-related technologies and social practices amplify the creativity and skills of individuals who affordably develop digitally self-made objects, e.g., unique-by-design objects designed by 3D modelling software and generated by 3D printers or networked smart objects equipped with microcontrollers dealing with context information via sensors and actuators. Two network effects catalyse DiDIY: what is custom produced by an individual could be the outcome of contributions from a worldwide community of developers sharing their interest towards open innovation, thus operating as knowledge multiplier; what is made available here and now by a smart object could be the aggregation of signals from a set of sources in the network, thus operating as information extender.

The Project will study how DiDIY is:

- reshaping organization and work, education and research;
- impacting on social and legal systems;
- changing creative design and ethics.

The development of a systemic interpretation is the challenge for the multidisciplinary Project team, which will collaboratively explore a complex phenomenon with implications on identity, privacy, reputation, responsibility and safety and will offer a roadmap fostering a DiDIY-based human-centric European development.

Data acquisition in the Project will consist of surveys, questionnaires, interviews and focus groups.

3. DURATION OF THE RESEARCH ACTIVITIES

Project activities will last 30 months from 01/01/2015 to 30/06/2017.

4. RISKS OR INCONVENIENCES

No risk is foreseen. You are only requested to be available to participate.

5. BENEFITS

It is likely that you will not receive any personal benefit for your participation in this study besides possibly learning more about digital do it yourself. With your participation you will make a substantial contribution to an understanding how the phenomenon of digital do it yourself is currently perceived and shaped, and could plausibly evolve.

6. PRIVACY AND CONFIDENTIALITY

Responses you give in the questionnaires, interviews, workshop and focus group will be recorded. Your recorded data will not include any personal identification; hence it will not be possible to identify you afterwards.

Information will be processed during the phase of data analysis and will be shown in project reports. It will not be possible to identify the source of the information. The results of this investigation may be published in scientific journals or conferences and may be used in further studies. Nothing of the provided personal data will be handled out to third parties.

The authorization for the use and access to this information is valid until the end of the study unless you decide to cancel it before. If you should decide to deny your consent, please contact the leading investigator and let her/him know of your intention of leaving the study.

Your decision to whether or not give your authorization for the use and diffusion of the information provided by you is completely voluntary. However, if you do not provide the investigators with this authorization now or if you cancel it in the future, you will not be able to participate in this study.

7. CONTACT PERSONS

In case of any issue involving you in your role of participant of this research study, you are invited to inform the Project Coordinator, prof. Luca Mari, via email, lmari@liuc.it.

8. CONFIRMATION

Your participation in this study is only possible if you freely and independently sign this consent to authorize us to use the data you provide. If you do not wish to do so, please do not participate in this study.

I hereby declare:

- I am 18 years or older and am competent to provide consent;
- I have been fully informed about the aims and purposes of the DiDIY Project. I understand that there is no compulsion to participate in the DiDIY Project and, if I choose to participate, I may at any stage withdraw my participation;
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me;
- I agree that my data (collected by surveys, questionnaires, interviews or focus groups) is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity;
- I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team;
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights;
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty;
- I understand that my participation is fully anonymous and that no personal details about me will be recorded;
- information may be shared between any of the other researcher(s) and partners participating in this Project in an anonymous form. All information I give will be treated as confidential. The researcher(s) will ensure to preserve my anonymity;

- I have received a copy of this agreement.

This consent form is made pursuant to the relevant national, European and international data protection laws and regulations and personal data treatment obligations. Specifically this consent document complies with the following laws and regulations:

- EC Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

……

Name and surname of participant

(if the participant is minor: also name and surname of parent/authorized adult's participant)

……

Place, date and signature of participant or, if minor, of parent/authorized adult's participant

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

……

Name and surname of the researcher

……

Place, date and signature of the researcher: