



D1.9 FIRST ETHICAL REPORT

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Executive summary

Deliverable D1.9, First ethical report, provides information on key ethical issues concerning research activities as identified and established according to EU and national directives, relating to the first 15 months of the DiDIY Project. It is focused on the procedures adopted by the beneficiaries to carry out the action in compliance with (i) ethical principles (including the highest standards of research integrity – as set out, e.g., in the European Code of Conduct for Research Integrity – and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct); (ii) applicable international, EU, and national law.

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Introduction

Purpose and state

This deliverable provides information on key ethical issues concerning research activities as identified and established according to EU and national directives, relating to the first 15 months of the Project. It is focused on the procedures adopted by the beneficiaries to carry out the action in compliance with (i) ethical principles (including the highest standards of research integrity – as set out, e.g., in the European Code of Conduct for Research Integrity – and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct); (ii) applicable international, EU, and national law.

One anomaly must be pointed out in this version of the deliverable. As specified in the Grant Agreement, the deliverable was due by M15. According to an automatic email received by the PC on 1 February 2016, a brand new Work Package, WP9, was created related to the ethics requirements of the Project. Starting from Table 1.4, “Ethics Requirements”, of Annex I of the GA, 12 deliverables were created, each referring to an ethics requirement in the Table. All these new deliverables are attributed to the newly created WP9, and according to the Participant Portal online system have the Dissemination Level “Confidential, only for members of the consortium (including the Commission Services)” (differently from D1.9, which is Public), have LIUC as Lead Beneficiary, and are peculiarly stated to be submitted by 1 April 2015. Despite the redundancy, the PC agreed with the PO that both D1.9 and the new D9.* will be submitted, all of them by 30 April 2016, i.e., M16.

Terms and acronyms

EC	European Commission
REA	Research Executive Agency
GA	Grant Agreement
CA	Consortium Agreement
SB	Steering Board
MO	Management Office
WP	Work Package
H	Humans
POPD	Protection of Personal Data
OEI	Other Ethics Issues



1. Description

In accordance with the information related to the ethics requirements of the Project and the above mentioned principles, regarding the periodic ethical report, it is appropriate to set up a preliminary framework regarding the scope and the subject of this specific activity.

First, it should be pointed out that the general relevant principles are, on one hand, those of ethics nature and, on the other hand, those following the application of international, European and National laws.

Second, the Project Grant Agreement, which regulates and defines the Project activity, contains a list of ethics requirements that represent relevant operative criteria.

Conventional norms, that can be found in the regulation of the Project and that deal with these ethics requirements, define the recruitment procedures of participants and the criteria on which such recruitment are based. The same conventional norms contain the informed consent procedures, that are mandatory to allow the participants to data collection activities to answer questionnaires with the requested data. These procedures should necessarily refer to the purpose of the research, the duration of the research, the procedures and modes of participation of the persons recruited, the prediction of the possible risks and, above all, the need to indicate the procedures for the protection of the collected data. Besides that, it seems necessary to check whether there is a close and ethically relevant relationship with the “right to be forgotten” for the data collected from each participant. Moreover, from the ethical point of view, the verification of regularity and correctness of the procedures adopted will necessarily focus on the examination of any problems resulting by the automatic identifiability of the participants, on the basis of gender, religious or political beliefs, and sexual orientation.

It should also be pointed out that the issues related to ethics within the Project were categorized according to a scheme – based on 12 characteristics that we identified – to which we briefly refer as “ethical environment” or “scope of ethical relevance”. Specifically, the criteria on the basis of which the ethical verification must be carried out and formulated are focused on:

1. evaluation of risks of ethical nature, which can be unexpectedly generated and, therefore, are not predictable at the beginning of the research;
2. evaluation and analysis of the procedures and criteria to be used to identify and recruit the participants to the research;
3. evaluation of detailed information to be provided in relation to the informed consent procedures;
4. evaluation of the detailed information provided about the procedures used for data collection, for data storage, for data protection, for the eventual elimination of data collected, always checking that the data processing complies to the national legislation of the individual countries in which the data is collected and processed, together with the European Union legislation;
5. verification of the existence of the application of elements of identification, directed to verify the environment where the data were collected, such as time, date and place of data collection, the type of module used, and an indication of the subdivision of the data categories. In particular, it must be verified whether the candidates were made aware that a recent jurisprudence from the European Court of Justice introduced “a right to be forgotten”



- which implies that identifiers must be deleted on time. Therefore, depending on certain conditions, it should be considered that those who provided data can require the application of this new law;
6. adoption of informed consent procedures and their actual implementation;
 7. verification of the communication of the details on types of treatment of sensitive data, of medical and psychiatric nature, and – in any case – data that are not related with the purpose of research;
 8. presence of specific authorization given through the informed consent procedures to collect and process personal data;
 9. anticipation of the submission to the REA of the authorizations, as well as approvals for the collection of personal data from the competent officials for the protection of data within the University as well, although only as an eventuality, from the National Authority for the protection of privacy and of personal information;
 10. anticipation of the submission to the REA of the authorizations of the approval of the competent authorities, which concern individual ethical issues different from the collection of personal data;
 11. designation of an external independent Ethics Advisor, appointed to oversee the potential ethical concerns involved in the research. The Ethics Advisor will prepare and submit to the REA a periodic report together with the financial accounts;
 12. adoption of models for the collection of informed consent as well as information sheets that should have a language and terms that are easily understood by the participants in the research.

Starting from the examination of these 12 specific characteristics, it is clear that the ethics report will follow three basic guidelines. The first one will focus on general ethical issues, other than those involved in the specific research. The second one will focus on the relationship of subjective nature of, on the one hand, the operators who carried out research activities and, on the other hand, of the recruited participants, in order to identify a unified criterion that concerns the integrity of the subject under the ethical aspect. The third one will deal with the modalities of protection of personal data.

In this specific case, we should necessarily point out that each specificity must be related to the kind of research and to the subject that such research involves, because the respect of ethical criteria, especially as those specified above, should be aligned to the research, so that, in case of absence of potential risks – as it happens in some aspects of the program under verification – there is only the need to specify that those risks and their potential occurrence are absent.

Therefore, on the basis of what we have described above, examining modalities and criteria adopted in the Project, it should be pointed out that among the partners of the consortium (University of Westminster, Manchester Metropolitan University, Amerikaniko Kollegio Anatolia, Politecnico di Milano, Sticking Free Knowledge Institute, Ab.Acus srl, Università Carlo Cattaneo – LIUC), only three of them conducted activities of data acquisition and, therefore, that only in relation to such partners it is necessary to proceed with the ethics verification.

It is necessary to preliminarily point out that national laws involved, to which some of the criteria refer to, are those of the Italian Republic and the Kingdom of the Netherlands, since, as we said, the other participants, belonging to the national legislation of the United Kingdom, Greece, and again



the Italian Republic (Politecnico di Milano), did not perform any activities of data acquisition. We can, therefore, conclude that, with respect to the Project partners who have not carried out any recruitment and data collection activities, there will be no verification of ethical nature.

The specific categories of ethical nature mentioned above must be taken into consideration, individually, for each Project partner, in order to produce a number of reports that it is the same to the formal list of the necessary requirements.

An additional specification of procedural nature concerns the way by which the activities carried out by individual partners have been examined. A questionnaire containing the information and, therefore, the essential questions to set up the ethical framework described above, was sent to each of the partners. This method of investigation, within the subject of the research program, whose ethical context we are analysing, appears to be coherent with the general indications and with the activity of ethical advisory and coaching.

The questions, contained in the form to which the partners had to formally answer, concerned the following general aspects:

- whether activities of data acquisition have been carried out;
- the procedures and criteria for recruitment;
- the management of the collected data.

The questionnaire was focused on the issues and specific criteria listed above, reproducing precisely the ethics investigation layout required for the program.



2. H - Requirements No. 01

Ethics Requirement Description

Details on the procedures and criteria that will be used to identify/recruit research participants must be provided.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the identification procedures and criteria, in reference to the risks mentioned above, appear correct and coherent with what expected in similar cases.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the identification procedures and criteria, in reference to the risks mentioned above, appear correct and coherent with what expected in similar cases.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the identification procedures and criteria, in reference to the risks mentioned above, appear correct and coherent with what expected in similar cases.



3. H - Requirements No. 02

Ethics Requirement Description

Detailed information must be provided on the informed consent procedures that will be implemented.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, appear correct and coherent with the procedures expected in similar cases.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, appear *limited to the activity of data collection and however included in the activities described in section 1*.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, appear correct and coherent with the procedures expected in similar cases.



4. H - Requirements No. 03

Ethics Requirement Description

Details on incidental findings policy must be provided.

Verification of the activities carried out by partner Sticing Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the policy, in reference to the risks mentioned above, *although not specifically considered, is partially provided by the activities described in section 1.*

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the policy, in reference to the risks mentioned above, *although not specifically considered, is partially provided by the activities described in section 1.*

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the policy, in reference to the risks mentioned above, *although not specifically considered, is partially provided by the activities described in section 1.*



5. POPD - Requirements No. 04

Ethics Requirement Description

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.

Verification of the activities carried out by partner Sticing Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, appear coherent with the procedures expected in similar cases.



6. POPD - Requirements No. 05

Ethics Requirement Description

A number of identifiers (not only related to the identify of the participants but also as regard to the environment in which the data was collected: date of collection, format, hour, location, metadata sets, etc). These aspects must be considered and adequately documented by the applicants. More specifically, the applicants must be made aware that a recent jurisprudence from the European Court of Justice introduced “a right to be forgotten” which implies that identifiers must in time be deleted. The applicants must provide a proper process in order to consider this novel right and subsequent obligations.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.



7. POPD - Requirements No. 06

Ethics Requirement Description

Detailed information must be provided on the informed consent procedures that will be implemented.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, *although not specifically considered*, appear coherent with the procedures expected in similar cases *and are partially provided by the activities described in section 1*.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the information procedures, in reference to the risks mentioned above, appear coherent with the procedures expected in similar cases.



8. POPD - Requirements No. 07

Ethics Requirement Description

Justification must be given in case of collection and/or processing of personal sensitive data.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1.*

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, appear coherent with the corresponding general criteria.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, appear coherent with the corresponding general criteria.



9. POPD - Requirements No. 08

Ethics Requirement Description

Copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer / National Data Protection authority must be submitted to the REA.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*



10. OEI - Requirements No. 09

Ethics Requirement Description

The applicants must assess mission/function creep risks, document and mitigate them.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures of data collection, in reference to the risks mentioned above, appear correct and coherent with the procedures expected in similar cases.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures of data collection, in reference to the risks mentioned above, appear correct and coherent with the procedures expected in similar cases.

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures of data collection, in reference to the risks mentioned above, appear correct and coherent with the procedures expected in similar cases.



11. OEI - Requirements No. 10

Ethics Requirement Description

Copies of ethical approvals by the competent authorities must be submitted to the REA.

Verification of the activities carried out by partner Sticking Free Knowledge Institute

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*

Verification of the activities carried out by partner Ab.Acus

According to the responses to the questionnaire mentioned in section 1, it emerges that the procedures, in reference to the risks mentioned above, *although not specifically considered, are partially provided in the activities described in section 1 and in the structure of the Project.*



12. OEI - Requirements No. 11

Ethics Requirement Description

An external independent Ethics Advisor must be appointed to oversee the ethical concerns involved in this research. A report by an Ethics Advisor must be submitted to the REA with the financial reports.

Verification of the activities carried out by the consortium

The procedure of identification, appointment, and planning of the activities of the Ethics Advisor is coherent with the ethical principles of the Project.



13. OEI - Requirements No. 12

Ethics Requirement Description

Templates must be provided for Informed Consent Forms and Information Sheets (in language and terms understandable to the participants).

Verification of the activities carried out by partner Sticing Free Knowledge Institute

The adopted procedures *partially fulfill the specified criterion, and are substantially provided in the previous activities*, so that an acceptable result is obtained.

Verification of the activities carried out by partner Università Carlo Cattaneo – LIUC

The adopted procedures *partially fulfill the specified criterion, and are substantially provided in the previous activities*, so that an acceptable result is obtained.

Verification of the activities carried out by partner Ab.Acus

The adopted procedures *partially fulfill the specified criterion, and are substantially provided in the previous activities*, so that an acceptable result is obtained.