Mapping Normative Frameworks

of EThics and Integrity of Research

D1.3 Data management plan

Mapping Normative Frameworks of EThics and Integrity of REsearch

Data management plan
D1.3

Project:	Mapping Normative Frameworks of EThics and Integrity of REsearch
Project acronym:	EnTIRE
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Deliverable leader:	Guy Widdershoven
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0.2	30-10-2017	Final	Guy Widdershoven
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List of abbreviations:

SHA: Secure Hash Algorithm
AES: Advanced Encryption Standard
URL: Uniform Resource Locator
DOI: Digital Object Identifier
UTF: Unicode Transformation Format
AQL: Structured Query Language
CC: Creative Commons
API: Application Programming Interface
SSL: Secure Sockets Layer
HTML: HyperText Markup Language

Contents

Introduction

This deliverable, due in the sixth month of the project, provides a first version of the EnTIRE data management plan (DMP). The document describes how the collected and generated data will be handled during and after lifecycle the project. The DMP will be updated, where necessary during the EnTIRE project. This document is based on the Template for the ERC Open Research Data Management Plan (DMP)[1].

Background

The EnTIRE project aims at providing a mapping of the Research Ethics (RE) and Research Integrity (RI) normative framework which applies to scientific research conducted in the EU and beyond. The mapping in this project generates various forms of data. The data includes but is not limited to RE+RI rules and procedures, educational materials, best practices, and illustrative case studies in Europe. Organizing and disseminating this data is the primary objective of this project. During this project the scope of the data will be decided upon by the stakeholders (WP2). The data will be compiled from existing closed and open data sources. New data will also be produced, mostly in relation to the interpretation of existing data. The size of the data is expected to gradually increase and reach approximately 2,500 items after 4 years.

1. Data summary

1.1 Purpose of the data collection/generation

The overall aim of the data collection within the project is to map the RE+RI normative framework and make it freely available and (re)usable. For this purpose Work Package (WP) 2, 3, 4 and 5 are dedicated to data collection.
The purpose of this data collection is:
1) to explore RE+RI experiences and practices, defining the boundaries of data to be collected, and developing a mapping structure adapted to user needs (WP 2, stakeholder consultation).
2) to gather information on: relevant normative elements, including RE+RI rules and procedures, educational materials, illustrative cases, and relevant institutions across EU countries (WP 3-4-5).

[1] Based on 'Guidelines on FAIR Data Management in H2020', version 3.0. 26.07.2016.

1.2 Relation to the objectives of the project

Organizing and disseminating the data is the primary objective of this project. This will be achieved by developing a Wiki platform which will collect all the data gathered during the project and present them in a user-friendly and needs-oriented way. The data collected are mostly publicly available but not easily findable or searchable. The goal of the project is to retrieve those data from different sources and make them available on one platform (purpose 2), owned by the community of users and tailored to its specific needs (purpose 2).

1.3 Types and formats of data generated/collected

For a detailed overview of the types and formats of data collected and generated please see Annex1 (Detailed DMP). Where data will be made publicly available, FAIR principles are followed as indicated.
The mapping in this project generates mainly textual data. Other forms of produced data include software modifications that will be used to employ and optimize the platform. This data will be made publicly and freely available on current open source repositories according to the original licenses of the software packages (e.g. Semantic MediaWiki).
For each WP a short description of the types and formats of data collected is provided here below:
1) WP2: Stakeholder consultation
The data collected in WP 2 consists of focus group recordings, transcripts, and basic data from a survey (using EUSurvey tool) of focus groups participants' basic background characteristics.
2) WP3: Guidelines and regulations on RE&RI in the European Union
The data collected in Work package 3 will be composed of text files which are part of the public domain. These data will be composed by: guidelines, standards, laws, and codes in European countries.
3) WP4: Resources for RE+RI
The data collected in Work package 4 will be composed of publicly available data on 1) training opportunities for Research Ethics and Research Integrity (RE+RI) and openly available training materials.
4) WP5: Cases, casuistry and scenarios
The data collected in Work package 5 will be composed by RE+RI case references (including web URLs, DOIs and standard academic citations) and case tags, which will result from searches in different potential sources, e.g. academic literature, reports of RE+RI committees, professional regulators, grey literature, media outlets and the blogosphere. An additional type of data developed by WP5 involves fictional scenarios. Some of these are generated by users and uploaded by users themselves: Browse data: Resource - The Embassy of Good Science.

1.4 Origin of the data

Most of the data will be gathered from existing sources (closed and open ones). New data will also be produced (e.g. when consulting stakeholders and creating casuistry for educational purposes).

A general description of the origin of the data can be found here below:

1) WP2: Stakeholder consultation
   - Face-to-face focus groups and in an online survey from 16 people in each of the following countries: Spain, the Netherlands and Croatia;
   - Online focus groups and in an online survey from approximately 350 people from other EU countries.
2) WP3: Guidelines and regulations on RE &RI in the European Union
   - Google, Google Scholar and PubMed;
   - Relevant RE RI organization across Europe.
3) WP4: Resources for RE+RI
   - Scientific articles, reviews, books, examples and training materials, available on MEDLINE and SCOPUS databases (current output from pilot search strategies include 22426 and 16194 publications, respectively);
   - Specialized sites, like ORI (Office for Research Integrity) website (https://ori.hhs.gov/) and RRI Tools (https://www.rri-tools.eu/);
   - Website from universities; websites of EU projects, identified in EU project website http://cordis.europa.eu/;
4) WP5: Cases, casuistry and scenarios
   - Academic Literature;
   - Reports by RE+RI Committees and Regulatory Bodies;
   - Grey Literature;
   - Media Outlets;
   - The Blogosphere;
   - Online Repositories;
   - WP2's Focus Group Sessions (used for inspiration but no real quotes or cases)

1.5 Expected size of the data

The data uploaded on the final platforms is expected to gradually increase and reach approximately 2,500 unique persistent items after 4 years (WP 3- 5 will each produce approximately 500 unique content items). The community will be expected to produce a thousand items. As multiple formats will be allowed (e.g. textual data, images, video, sound), the expectation is that the resulting database will be around 2.5 Gigabytes in size.

1.6 Outline the data utility

The collected data will be relevant for the stakeholders (RI+RE community). This means that the data collected will be relevant both for researchers, who will find support for good research practices in the content available on the EnTIRE platform, and for the general public, who will be able to use the platform to find easily accessible and user friendly information on research subject related information. Moreover the software modification data will be available for future knowledge management EU founded projects.

2. FAIR data

The project will use FAIR data principles[2] where possible for public data. An analysis was performed on all data generated. A detailed analysis can be found in Annex 1.

2.1 Making data findable, including provisions for metadata

2.1.1 Discoverability of data (metadata provision)

The metadata construction of The Embassy is provided in detail in the semantic mediawiki 'manual'. For example, Theme page has an 'About' section (which is a property, all properties can be viewed here), which is a text (an overview of Types is given here) and all about sections can be either retrieved and modified on the platform itself (the source code of any page shows its properties), or automatically extracted via the platform (like this) or via the API. All meta data is available on each page of The Embassy (www.embassy.science) via the "view page source" function. To access this, users just need to right click anywhere on a page and select "view page source". Metatags (e.g. properties) are displayed at the top on this page source information.

2.1.2 Identifiability of data

The URL naming on the platform is persistent for content. Digital Object Identifiers have not however been used. We hope to be able to implement DOIs in the future through the work of The Embassy Foundation.

[2] M. D. Wilkinson et al. 2016. The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data* 3:160018.

2.1.3 Naming conventions

Naming conventions for the theme pages are as follows:

The European Code of Conduct for Research Integrity is used as a framework for the 'Good Practices': Browse data: Theme - The Embassy of Good Science

A ranking of Major and Minor misbehaviours is used as a framework for the 'Misbehaviours and misconduct': Browse data: Theme - The Embassy of Good Science

Bouter, L.M., Tijdink, J., Axelsen, N., Martinson, B.C. and Ter Riet, G., 2016. Ranking major and minor research misbehaviors: results from a survey among participants of four World Conferences on Research Integrity. Research Integrity and Peer Review, 1(1), p.17.

Categories and suggested tags for use on individual pages can be viewed on the pages for adding these elements:

Create Theme - The Embassy of Good Science

Create Report - The Embassy of Good Science

Create Resource - The Embassy of Good Science

Create Instruction - The Embassy of Good Science

2.1.4 Approach towards search keyword

Two main approaches are employed:

1) Keywords will be included in the page of the online platform to increase searchability by common search engines. These keywords will be based on the analysis of terminology in RE+RI.

2) Users on the platform will be given the opportunity to add tags to content. This folksonomy approach is more flexible and dynamic and ensures that over the longer term, keywords match what people are looking for themselves.

2.1.5 Approach for clear versioning

The Mediawiki software has a versioning system which tracks every modification made on the platform. This can be found on the platform at: Recent changes - The Embassy of Good Science

2 2.1.6 Metadata creation

2.1.6 Metadata creation

Users can add themes, reports, resources and instructions to The Embassy. Metadata categories for each of these can be viewed on the following links:

Create Theme - The Embassy of Good Science

Create Report - The Embassy of Good Science

Create Resource - The Embassy of Good Science

Create Instruction - The Embassy of Good Science

Free tagging is also possible on The Embassy, improving flexible re-use, searchability and analysis of data.

2.2 Making data openly accessible

All content collected for The Embassy is organised and available on the platform www.embassy.science. Only qualitative data collected as part of the stakeholder consultation is not open (due to privacy concerns). All public deliverables are available on a repository on the Embassy: Latest EnTIRE/Repository topics - The Embassy of Good Science

Open source software modification were published on online repositories and are available here:

- Front-end design elements - https://github.com/the-embassy-of-good-science
- Archived front-end design elements - https://doi.org/10.5281/zenodo.5925902
- Back-end design elements - https://github.com/the-embassy-of-good-science/the-embassy-platform
- Archived back-end design elements - https://doi.org/10.5281/zenodo.5925930

License - MediaWiki and The Embassy are licensed under the terms of the GNU General Public License, version 2 or later. Derivative works and later versions of the code must be free software licensed under the same or a compatible license. This includes "extensions" that use MediaWiki functions or variables; see https://www.gnu.org/licenses/gpl-faq.html#GPLAndPlugins Page 4 of 6 Open Research Europe 2022, null:null Last updated: 14 FEB 2022 for details. For the full text of version 2 of the license, see: https://www.gnu.org/licenses/gpl-2.0.html. For full details of the licensing see: https://github.com/the-embassy-of-good-science/the-embassy-platform/blob/master/COPYING

2.2.1 Ethical concerns related to publication

For sensitive data which will not be made publicly available, researchers can contact the relevant Work Package lead. Contact details and instructions will be present on the platform.
In order to avoid the risk of participants' personal knowledge of deviant cases being exposed to others the data collected by WP2 (stakeholder consultation) and WP5 (cases casuistry and scenarios) will not be fully published. Special measures will be adopted to ensure the protection of privacy and confidentiality:

1) Cases and quotes from the focus groups were not used on The Embassy due to privacy concerns. Themes from the focus groups however were used for inspiration for hypothetical scenarios.
2) Full transcripts of the face-to-face and online focus groups interview will not be published and will only be accessible for authorized study personnel;
3) Audio recordings of face-to-face focus groups will be destroyed after they have been transcribed and quality checks have been conducted. A data erasure software will be used in order to assure permanent erasure.
4) Any sensitive data collected will be stored electronically in 'Dark Storage', a maximum security data storage facility at VUmc.
5) Only openly available cases were used on The Embassy. The Embassy summarizes cases but links out to the open resource

Foreseeable privacy and related and ethical concerns are also addressed in Annex 1.

2.2.2 Methods or software tools are needed to access the data

The data can be accessed using a conventional internet browser or a an open source (i.e. Python[3]) or closed source software package (Matlab[4], Mathematica[5]). Data will be available on the platform but it will also be possible to export documents and data for on and offline use. All members of the community working on the platform will commit data based on the latest Creative Commons License (4.0) ensuring an open data and open access approach. This adheres to the license requirements of Wikimedia[6].
Licensing information can be accessed here: Terms of service - The Embassy of Good Science

[3] https://www.python.org/
[4] https://www.mathworks.com/products/matlab.html
[5] https://www.wolfram.com/mathematica/
[6] https://wikimediafoundation.org/wiki/Resolution:Licensing_policy

2.3 Making data interoperable

An important technical addition to the platform is the Semantic Mediawiki extension (https://www.mediawiki.org/wiki/Extension:Semantic_MediaWiki). This makes it possible to organize content in a smart way ("*semantic web*"). The information is easily searchable and different sources of information can be linked to each other. The system works well for people and machines, according to the FAIR principles. This also makes it possible to give automated systems access to the knowledge that is collected on the platform. A complete overview of the open-source software used can be found on the platform itself (https://embassy.science/wiki/Terms_of_service#t_o_s-intellectual_property).

All data gathered and produced for the Embassy Platform is viewable and interoperable. Metadata categories for each of these can be viewed on the following links:

Create Theme - The Embassy of Good Science

Create Report - The Embassy of Good Science

Create Resource - The Embassy of Good Science

Create Instruction - The Embassy of Good Science

2.4 Increase data re-use (through clarifying licenses)

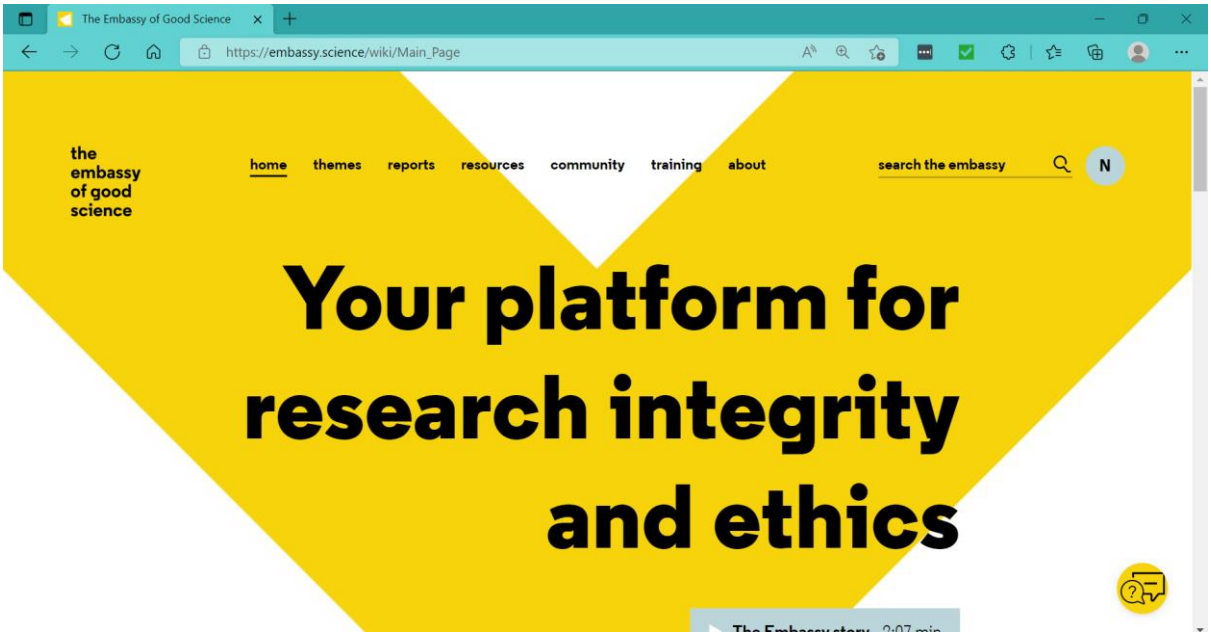
All the data uploaded on the platform will be made available through the Creative Commons License structure where applicable. In cases of copyright, data will be linked to instead and deduced work will be made available under the Creative Commons License where possible.

Except for some exceptions where privacy concerns outweigh data availability (for the specifics, see section 2.2.1 and Annex 1), all data will be made available for re-use.

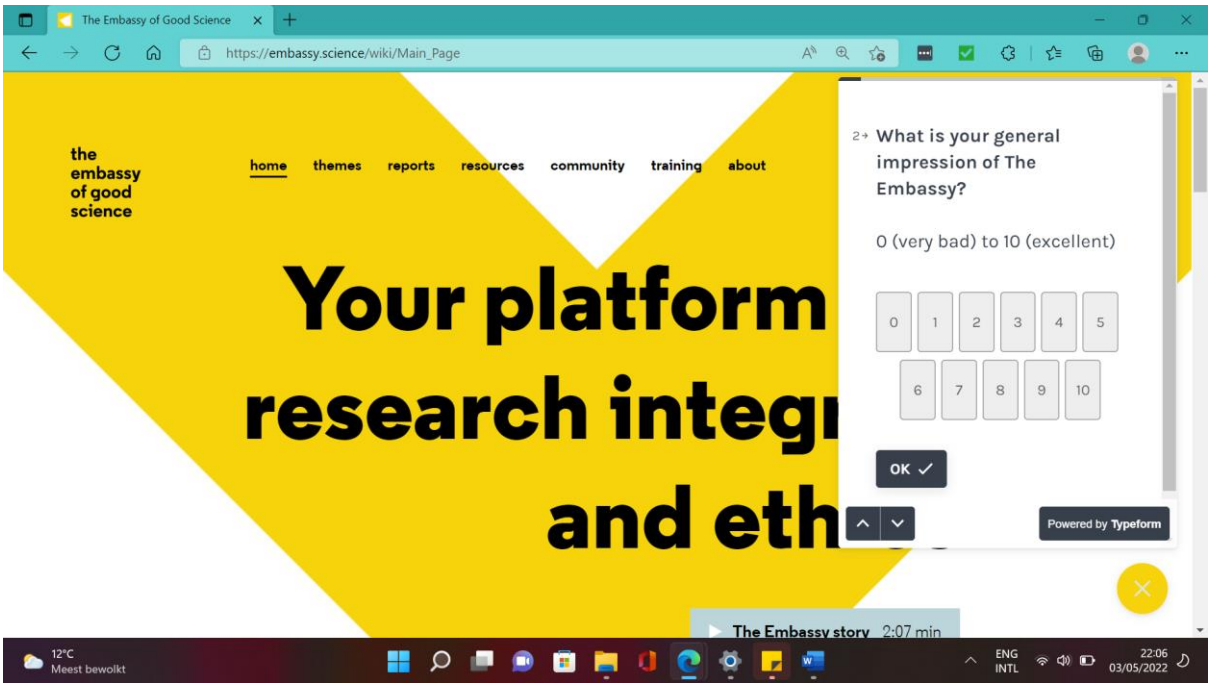
Licensing information can be accessed here: Terms of service - The Embassy of Good Science

2.4.1 Data quality assurance processes

A continuous evaluation mechanism is integrated into the platform (yellow speech bubble icon bottom right-hand corner of each page (see figure below).



This leads to a survey on the quality of the platform and provides a facility to report bugs.



3. Allocation of resources

In this project the data is FAIR by design. This will in the long term reduce the upkeep costs of the platform. No additional costs are associated with FAIR data management. As the availability of the data can be expected to be valuable to many stakeholders, a plan will be created to ensure long term preservation and distribute the long-term upkeep costs amongst the stakeholders (WP 7).

Data management is initially the primary responsibility of project co-ordination (WP 1). During the project, this responsibility is gradually distributed to the community (WP 7). A Foundation has been established to ensure long term preservation and upkeep of The Embassy: https://embassy.science/wiki/About#foundation

4. Data security

4.1 Data recovery, secure storage and transfer of sensitive data

The ICT partner, gesinn.it (nr.2 GI) is responsible for data security on the platform. User authentication is through ORCID login. Security and Privacy is described in our privacy statement, terms of service, and take down policy:

https://embassy.science/wiki/Privacy_statement

Terms of service - The Embassy of Good Science

Take down policy - The Embassy of Good Science

The Embassy enables clear versioning, and data is stored long term.

Furthermore, The Embassy only uses functional cookies and does not track users. This means the user experience cannot be tailored according to prior platform usage. This was a decision made to comply fully with GDPR and to maintain the privacy of users.

https://embassy.science/wiki/Privacy_statement#p_s_cookies

Transfer of sensitive data will be made by establishing a secure connection (SSL).
Any sensitive data which might result from the stakeholder consultation (WP2) will be stored in 'Dark Storage', a maximum security data storage facility at VUmc (NL).

5. Ethical aspects

Most of the data collected within the project come from the public domain.
However, the project involves research with human participants (questionnaire, focus groups). Participants will not be exposed to the risk of physical injury, financial, social or legal harm, and potential psychological risks will not exceed the daily life standard.
Privacy and confidentiality of research participants and of the members of the community on the platform will be protected. Before publishing information on the EnTIRE platform, confidentiality and privacy issues will always be addressed. If necessary, informed consent will be obtained (as specified in section 2.2.1 and Annex 1).
We are not aware of and do not expect any potentially critical ethical implications of the research results such as the protection of dignity, autonomy, integrity and privacy of persons, biodiversity, protection of the environment, sustainability or animal welfare. The

proposed research does NOT include research activity aimed at human cloning, intended to modify the genetic heritage of human beings, to create human embryos, or involving the use of human embryos or embryonic stem cells. This research proposal does NOT include any security sensitive issues.
Data will primarily be stored in Europe based servers. No primary results will be exported to the US without their primary location being on the EU soil. Ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out.
The Ethics deliverables have been submitted on September 30th and attached to this document (Annex 2).

APPENDIX 1

Detailed data management plan

Detailed data management plan

List of abbreviations:
SHA: Secure Hash Algorithm
AES: Advanced Encryption Standard
URL: Uniform Resource Locator
DOI: Digital Object Identifier
UTF: Unicode Transformation Format
AQL: Structured Query Language
CC: Creative Commons
API: Application Programming Interface
SSL: Secure Sockets Layer
HTML: HyperText Markup Language

WP	Description	Data resource	Primary format	Privacy concerns	Ethical concerns	Size expectation	Availability	Security	Centralized back-up	Public location	F1 Unique and Persistent	F2 Metadata	F3 Metadata Registered and Searchable	F4 data identifier	A1 standard open protocol	A2 Accessible	I1 Language	I2 Vocabularies	I3 References	R Re-usable
WP1	Management (public disclosure)	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP1	Management (EU/Internal)	Report	PDF	Names	No	Small	Internal	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP1	Logo	Image	SVG	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	www.entireconsortium.eu										CC 4.0
WP1	Project website	Status update	HTML	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	www.entireconsortium.eu										
WP1	Management (public disclosure)	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP1	Management (EU/Internal)	Report	PDF	Names	No	Small	Internal	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP2	Research protocol	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP2	Research results	Report	PDF	Identifiable information	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform										
WP2	Research results	Interview recording	WAV	Identifiable information	Confidentiality	Small	Internal	Encryption (AES-256 bit) / SSL / Two-step verification	Online cloud storage (AES-256 bit)											
WP2	Research results	Transcript	DOCX	Anonymized identifiable info.	Confidentiality	Small	Internal	Encryption (AES-256 bit) / SSL / Two-step verification	Online cloud storage (AES-256 bit)											
WP2	Informed consent	Contract	Physical docun	Identifiable information	Confidentiality	Small	Internal	Physical storage												
WP2	Informed consent	Contract	Physical docun	Identifiable information	Confidentiality	Small	Internal	Physical storage												
WP2	Metadata/Vocabulary	Wiki-article	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI		Platform	UTF-8	HTML	Platform	English (US)	Platform		CC 4.0
WP2	Research results	Result database	MySQL	Anonymized identifiable info.	Confidentiality	Small	Public	SSL	Online cloud storage (AES-256 bit)	Platform	URL	Present	Platform	UTF-8	SQL	Platform	English (US)	Platform		CC 4.0
WP3	Research protocol	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP3	Overview of search selection	Search database	XLSX	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL	Search terms	Platform	UTF-8	XLSX	Platform	English (US)	Platform		CC 4.0
WP3	Selected documents	Document	URL	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL	Description	Platform	UTF-8	HTML/API	Platform	English (US)	Platform		CC 4.0
WP3	Archive of selected documents	Document	ZIP	No	No	Large	Internal	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP3	Research results	Report	PDF	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform										
WP3	Analysis of documents	Wiki-article	HTML	No	No	Medium	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI	Description	Platform	UTF-8	HTML/API	Platform	English (US)	Platform		CC 4.0
WP3	Metadata/Vocabulary	Wiki-article	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Primary authentication (SHA-256)	Platform	URL/DOI		Platform	UTF-8	HTML	Platform	English (US)	Platform		CC 4.0
WP4	Templates	Specification report	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Primary authentication (SHA-256)	Platform	URL/DOI			UTF-8	HTML	Platform	English (US)	Platform		CC 4.0
WP4	Research protocol	Report	PDF	No	No	Small	Public	Primary authentication (SHA-256)	Primary authentication (SHA-256)	Platform	URL/DOI									
WP4	List of training opportunities	Database	MySQL	Names	No	Small	Public	Primary authentication (SHA-256)	Primary authentication (SHA-256)	Platform	URL/DOI	Description	Platform	UTF-8	HTML/API	Platform	English (US)	Platform		CC 4.0
WP5	Metadata/Vocabulary/Tags	Wiki-article	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI		Platform	UTF-8	HTML	Platform	English (US)	Platform		CC 4.0
WP5	Research protocol	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP5	RE+RI fictional scenarios	Wiki-article	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI	Description	Platform	UTF-8	HTML/API	Platform	English (US)	Platform		CC 4.0
WP5	Unprocessed RE+RI cases	Wiki-article	HTML	Anonymized identifiable info.	Confidentiality	Medium	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI	Description	Platform	UTF-8	HTML					
WP6	Open source software	Software	Source code	No	No	Large	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Github										CC 4.0
WP6	Platform development and maintance	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP7	Community management	Report	PDF	Names	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)											
WP7	Community management	Wiki-article	HTML	No	No	Small	Public	Primary authentication (SHA-256)	Online cloud storage (AES-256 bit)	Platform	URL/DOI		Platform	UTF-8	HTML	Platform	English (US)	Platform		CC 4.0

APPENDIX 2

Ethics deliverables

This project has received founding from the European Union H2020 research and innovation programme under the grant agreement n. 741782.

Mapping Normative Frameworks of EThics and Integrity of REsearch

Ethics Requirements: H – Requirement N°. 1

WP 8 H – Requirement No 1.

Project details	
Project:	Mapping Normative Frameworks of EThics and Integrity of REsearch
Project acronym:	EnTIRE
Project start date:	01.05.2017
Duration:	48 months
Project number:	741782
Project Coordinator:	Vrije Universiteit Medisch Centrum (VUmc) Amsterdam

Deliverable details	
Work Package:	WP 8 Ethics Requirements
Deliverable description:	H – Requirement No 1.
Work package leader:	Vrije Universiteit Medisch Centrum (VUmc) Amsterdam
Responsible for the deliverable:	Natalie Evans
Submission date:	30.09.2017

Contents

Description of deliverable

EnTIRE conducts a mapping of the Research Ethics and Research Integrity (RE+RI) normative framework which applies to scientific research conducted in the EU and beyond. For the purpose of this project, it is necessary to gather data on and with humans, including: experiences and attitudes regarding RE+RI; opinions on the online platform; case studies regarding research misbehaviours; and best practice examples.

Primary data will be collected through questionaires and focus groups during the stakeholder consultation (WP2) and secondary (publically available) data will be collected by the work package gathering cases, casuistry and scenarios (WP5).

This deliverable provides:

1. Detailed information on the informed consent procedures that will be implemented for the participation of humans in the proposed activities (e.g. stakeholder consultation).
2. Templates of the informed consent forms and information sheet
3. Copies of the ethics approval or waiver forms for the stakeholder consultation from the Netherlands, Croatia and Spain.
4. Details about the approach for publishing publically available cases

Stakeholder consultation (Work package 1)

EnTIRE's stakeholder consultation will identify the RE+RI issues of concern to the stakeholders, practical experience with regulations and guidelines and other professional, institutional and national norms, resources, and existing best practices. The consultation will also be used to generate, and to reflect on, instructive cases from local practice.

The stakeholder consultation has been described in detail in Deliverable 2.1 -"Protocol for the phased multi-country stakeholder consultation". The consultation consists of face-to-face and online focus groups. Further details on the informed consent procedure, privacy and confidentiality, data management and ethics approval are given below.

Informed consent procedure

Participant information letter

Face-to-face focus groups

Stakeholders interested in participating in the face-to-face focus groups will be sent the below information sheet. Information in red must be adapted depending on the location of the focus group.

Invitation to participate in focus groups for the stakeholder consultation 'Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE)'

Dear Sir/Madam,

We at the EnTIRE project aim to create an online website that makes information about research ethics and research integrity easily accessible to the research community. This European Commission funded project seeks to include all stakeholders in a participatory way. As such, we are conducting an in-depth stakeholder consultation amongst people involved in research. We aim to consult: researchers, journal editors, national and local ethics/integrity committees, policy makers, representatives from industry (including pharmaceutical companies), and representatives from research funding organisations.

We would like to invite you to participate in these focus groups. By agreeing, you commit to participating in two separate discussions approximately one week apart in (insert city). They will be led by researchers from VU University Medical Center (in collaboration with The University of Split Medical School/European University of Madrid). As this is a Europe-wide consultation, the language of the focus groups will be English. Furthermore, one third of participants from the Dutch/Spanish/Croatian focus groups will be invited to participate in an additional focus group in Amsterdam that will bring together participants from parallel studies in (insert the two other countries) to discuss similarities and differences between countries.

All focus group discussions will take place in Autumn 2017. This letter contains details about the project and the stakeholder consultation so you can make an informed decision whether you would like to participate in the focus groups or not.

1. Aim of the focus groups

In the first focus group, we will discuss your experiences of research ethics and research integrity issues. This will allow us to develop an understanding of any difficulties you might encounter as well as ideas you might have on how you could be better supported in the future, particularly in regard to informational needs. For example, if researchers say they do not know data management guidelines, or the procedure for raising concerns about integrity of research practices, or, alternatively, have suggestions for improvement, we can identify those issues and suggestions as relevant for gathering information and putting this on the website.

The second focus group, taking place approximately two weeks later, will involve a presentation of the pilot version of the website and a discussion about its content and presentation. This will further help us understand if we need to collect any information additional to the preliminary data collection categories of: guidelines, codes, legislations, and standards; committees, training courses and expert advice and contacts; cases, casuistry and scenarios. Participants will also help us understand if we are presenting information in an optimal way or how this might be improved.

The third, potential, focus group, will bring participants together from the Netherlands Spain, and Croatian to discuss similarities and differences between countries. This will provide us with an understanding of the diversity of informational needs across different EU countries, and with suggestions on how to deal with them in presenting data on the website.

2. What is involved?

If you would like to participate, we will invite you to two focus group sessions at the VUmc, Amsterdam. The preliminary dates are:

Round 1. date of first focus group

Round 2. date of second focus group

Each of these focus groups will take about 2 hours.

There is also the possibility that you will be invited to a day-long workshop held at the VUmc, Amsterdam, that will bring together one third of the participants from the focus groups in the Netherlands, Spain, and Croatia.

Round 3. date of third focus group

If you cannot make these dates but would like to join the focus groups, we would still like to hear from you as we might conduct individual interviews with stakeholder groups under-represented in the focus group discussions.

Before attending the focus group, we will ask you to complete a short questionnaire (sent via email and taking about 15 minutes) about your background: gender, age, role (depending on the stakeholder group – e.g. academics will be asked their area of expertise (biomedical, social sciences, natural sciences, applied sciences) and position (PhD student, Research Associate, Assistant Professor, Professor, Head of Department), years of experience, nationality and country of residence. The questionnaire will also include a couple of open questions about what you know about research ethics and research integrity and what support is currently available to you.

3. Benefits and risks of participating

The direct benefits of participating in the research are that participants can share experiences and contribute to the development of the platform, thus being able to actively bring in and broaden their knowledge and experience; mostly, however, the benefits are indirect, they will be accrued by the research community as a whole which will benefit from access to a website that makes information about research ethics and research integrity easily accessible. The website will also potentially foster the uptake of ethical standards and responsible conduct of research in Europe, and ultimately support research excellence and strengthen society's confidence in research and its findings. One risk associated with the focus group is other people knowing the details about any research misconduct you might describe. Efforts to minimize this risk include asking all participants to return confidentiality agreements, and to avoid the use of identifying characteristics. In addition, the time commitment required for two (and potentially three) focus groups discussions may prove inconvenient.

4. If you do not want to join or want to stop the group conversation

Participation is voluntary. If you do not want to participate, you do not have to do anything and you are not required to let us know. If you decide to participate, you must sign the attached informed consent form and return it via email prior to the focus group. If you have agreed to participate but change your mind, you can of course withdraw at any point (including during the focus group discussions), we would ask you kindly to inform us if this is the case.

5. Use of data and dissemination of research findings to participants

The focus groups will be recorded. These recordings will be destroyed after they have been transcribed. Personal data, such as informed consent forms and answers to the questionnaire, will be stored separately from the discussion transcripts. Personal data will be destroyed within 6 months of the end of the focus group discussions. The transcripts of the focus groups will be kept for up to 15 years after the end of the study (in accordance with EU and Dutch/Spanish/Croatian data protection laws). All data is anonymised for analysis. The findings from the stakeholder consultation will also be published and made publically available on the Project's page on the European Commission research information portal:

http://cordis.europa.eu/project/rcn/210253_en.html

6. Financial aspects

There is no fee paid for participation, however all travel expenses will be reimbursed. If you are invited to the third, international focus group, your travel and accommodation will be reimbursed according to local university rules and you will receive 70 euros per diem to cover your expenses in the country.

7. Do you have any questions?

Please do not hesitate to contact the consultation project coordinator, Dr. Natalie Evans n.evans@vumc.nl, if you have any hestions.

Online focus groups

Online focus group participants will receive a similar information sheet to the face-to-face focus group participants, but tailored to the online procedure:

Invitation to participate in focus groups for the stakeholder consultation 'Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE)'

Dear Sir/Madam,

We at the EnTIRE project aim to create an online website that makes information about research ethics and research integrity easily accessible to the research community. This European Commission funded project seeks to include all stakeholders in a participatory way. As such, we are conducting an in-depth stakeholder consultation amongst people involved in research. We aim to consult: researchers, journal editors, national and local ethics/integrity committees, policy makers, representatives from industry (including pharmaceutical companies), and representatives from research funding organisations.

We would like to invite you to participate in this stakeholder consultation via participation in online focus groups.

By agreeing, you commit to participating in two online discussions, one focusing on your perspectives and experiences of research ethics and research integrity issues, the other focusing on your opinions about the proposed website. Each will take place over a period of two weeks, with a period of two weeks inbetween, with a new question posted every two days. You will receive an email each time a new question is posted.

You will interact with other participants anonymously and discussions will be facilitated and moderated by researchers from VU University Medical Center. As this is a Europe-wide consultation, the language of the focus groups will be English.

All focus group discussions will take place Jan-March 2018. This letter contains details about the project and the stakeholder consultation so you can make an informed decision whether you would like to participate in the online discussions or not.

1. Aim of the focus groups

In the first focus group, we will discuss your experiences of research ethics and research integrity issues. This will allow us to develop an understanding of any difficulties you might encounter as well as ideas you might have on how you could be better supported in the future, particularly in regard to informational needs. For example, if researchers say they do not know data management guidelines, or the procedure for raising concerns about integrity of research practices, or, alternatively, have suggestions for improvement, we can identify those issues and suggestions as relevant for gathering information and putting this on the website.

The second focus group, taking place approximately two weeks later, will begin with a short video about our proposed website, followed by a discussion about its content and presentation. This will further help us understand if we need to collect any information additional to the preliminary data collection categories of: guidelines, codes, legislations, and standards; committees, training courses and expert advice and contacts; cases, casuistry and scenarios. Participants will also help us understand if we are presenting information in an optimal way or how this might be improved.

2. What is involved?

If you would like to participate, we will invite you to two online discussions taking place over a two week period (with two weeks in between).

Round 1. date of first focus group

Round 2. date of second focus group

Before participating, we will ask you to complete a short questionnaire (sent via email and taking about 15 minutes) about your background: gender, age, role (depending on the stakeholder group – e.g. academics will be asked their area of expertise (biomedical, social sciences, natural sciences, applied sciences) and position (PhD student, Research Associate, Assistant Professor, Professor, Head of Department), years of experience, nationality and country of residence. The questionnaire will also include a couple of open questions about what you know about research ethics and research integrity and what support is currently available to you.

3. Benefits and risks of participating

The direct benefits of participating in the research are that participants can share experiences and contribute to the development of the platform, thus being able to actively bring in and broaden their knowledge and experience; mostly, however, the benefits are indirect, they will be accrued by the research community as a whole which will benefit from access to a website that makes information about research ethics and research integrity easily accessible. The website will also potentially foster the uptake of ethical standards and responsible conduct of research in Europe, and ultimately support research excellence and strengthen society's confidence in research and its findings. One risk associated with the focus group is other people knowing the details about any research misconduct you might describe. Efforts to minimize this risk include: anonymous interaction within the online discussion; asking all participants to return confidentiality agreements; and, asking participants to avoid using details that migth identify themselves or others. In addition, the time commitment required to respond to online comments may prove inconvenient.

4. If you do not want to join or want to stop the group conversation

Participation is voluntary. If you do not want to participate, you do not have to do anything and you are not required to let us know. If you decide to participate, you must sign the attached informed consent form and return it via email prior to the focus group. If you have agreed to participate but change your mind, you can of course withdraw at any point (including during the focus group discussions), we would ask you kindly to inform us if this is the case.

5. Use of data and dissemination of research findings to participants

Data from the online discussion threads will be collected by [name of online focus group provider], who have been selected based on their compliance with EU data protection acts and their ability to guarantee that participants can interact anonymously. Personal data, such as informed consent forms and answers to the questionnaire, will be stored separately from the discussion transcripts. Personal data will be destroyed within 6 months of the end of the focus group discussions. The discussion transcripts will be kept for up to 15 years after the end of the study (in accordance with EU and Dutch data protection laws). All data is anonymised for analysis. The findings from the stakeholder consultation will also be published and made publically available on the Project's page on the European Commission research information portal:

http://cordis.europa.eu/project/rcn/210253_en.html

6. Financial aspects

There is no fee paid for participation, however all travel expenses will be reimbursed. If you are invited to the third, international focus group, your travel and accommodation will be reimbursed according to local university rules and you will receive 70 euros per diem to cover your expenses in the country.

7. Do you have any questions?

Please do not hesitate to contact the consultation project coordinator, Dr. Natalie Evans n.evans@vumc.nl, if you have any hestions.

Informed consent and confidentiality agreement

On agreeing to participate, stakeholders from both the face-to-face and online focus groups will be sent a short online questionnaire (for details see Deliverable 2.1) and an informed consent and confidentiality agreement (see below) via email.

Informed consent and confidentiality agreement

Please read the statements below in connection with the research **'**Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE): stakeholder consultation' and sign if you are in agreement with all of the statements.

- I have read the information sheet.
- I was given the opportunity to ask any questions and any questions I did have were sufficiently answered.
- I had enough time to decide if I would join.
- I know that participation is voluntary. I also know that I can decide at any time that I would like to withdraw my participation and quit the study. I do not have to give any explanations.
- I give permission to make the sound recording.
- I give permission for collecting and using my data in the way and for the purposes stated in the information letter.
- I want to participate in this research.
- **I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session.**

Name:

Signature: Date: __ / __ / __

The questionnaire and informed consent and confidentiality agreement need to be completed before participation.

Privacy and confidentialty

One risk associated with the focus group discussions is other people knowing the details about any research misconduct described. Efforts to minimize this risk include: anonymous interaction within the online discussion; asking all participants to return confidentiality agreements; and, asking participants to avoid using details that migth identify themselves or others. Participants will also be reminded to respect privacy and confidentiality at the beginning of each and every focus group (both face-to-face and online).

Data management

The burden of responsibility for data protection lies with the Dutch partner (VUmc).

Face-to-face focus groups

Audio recordings of face-to-face focus groups will be destroyed after they have been transcribed and quality checks have been conducted, and only the transcripts will be archived.

Online focus groups

Data from the online discussions will be collected through third party software. A suitable party will be chosen in the next months, and will be selected based on their compliance with EU data protection acts and their ability to guarantee anonymity. A data processing agreement with this party will be constructed and signed.

Face-to-face and online focus group transcripts will have any identifying information removed as much as possible, and will only be accessible to authorized study personnel. Any sensitive data collected will be stored electronically in 'Dark Storage', a maximum security data storage facility at VUmc.

Ethics approval

Ethics approval or excemption documents have been obtained in the Netherlands (for the Dutch face-to-face and the multi-country online focus groups), Spain (for the Spanish face-to-face focus groups) and Croatia (for the Croatian face-to-face focus groups).

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www.vumc.nl/METc
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Dr. N. Evans
Metamedica, F vleugel/gebouw
De Boelelaan 1089a
1081 HV Amsterdam

VUmc

onderwerp	ons kenmerk	datum
niet-WMO advies	2017.404	10 augustus 2017

Geachte mevrouw Evans,

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum heeft uw onderzoek **Mapping Normative Frameworks for EThics and Integrity of Research (EnTIRE): Work Package 2 - Stakeholder Consultation** besproken in de vergadering van 08/08/2017.

Het onderzoek valt niet onder de reikwijdte van de Wet Medisch-wetenschappelijk Onderzoek met mensen (WMO).

Het oordeel is gebaseerd op de volgende documenten:

Sectie	Onderwerp	Versie
A1	aanbiedingsbrief	d.d. 26-07-2017
A1	commentaar METc	d.d. 10-8-2017
C1	onderzoeksprotocol	d.d. 26-07-2017
E11	informatiebrief	RE+RI stakeholders, version 1, d.d. 26-07-2017
E2	toestemmingsverklaring	version 1, d.d. 26-07-2017
F1	vragenlijst	EnTIRE vragenlijst
F1	vragenlijst	topicslijst voor focusgroepen

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum wijst u erop dat hoewel het ingediende onderzoek niet onder de reikwijdte van de WMO valt, andere wet- en regelgeving (mogelijk) wel van toepassing is, waaronder:

- WGBO (Wet Geneeskundige BehandelingsOvereenkomst);
- WBP (Wet Bescherming Persoonsgegevens), zie www.cbpweb.nl;

- Code Goed Gedrag (Gedragscode gezondheidsonderzoek: gebruik medische gegevens in wetenschappelijk onderzoek), zie www.federa.org;
- Code Goed Gebruik (Gedragscode Verantwoord omgaan met lichaamsmateriaal ten behoeve van wetenschappelijk onderzoek, 2011), zie www.federa.org;
- Biobanken: Reglement toetsing biobank VUmc, zie https://www.vumc.nl/afdelingen/METc/biobank/;
- WBO (Wet Bevolkings Onderzoek), zie http://www.vumc.nl/afdelingen/METc/wetgeving/wetbevolkingsonderzoek/.

To whom it may concern

We are pleased to confirm that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that an official approval of this study by our committee is not required.

The Medical Ethics Review Committee of VU University Medical Center is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598.

Met vriendelijke groet,
namens de Medisch Ethische Toetsingscommissie VU medisch centrum,

p.o.

prof. dr. J.A. Rauwerda, voorzitter

c.c.: afdelingshoofd metamedica (prof. dr. G.A.M. Widdershoven)

Hospital Universitario Fundación Alcorcón

SaludMadrid

Comunidad de Madrid

MODELO DE EVALUACIÓN ÉTICA. INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA

Dña. Ana María Tato Ribera, Secretaria del Comité Etico de Investigación Clínica del Hospital Universitario Fundación Alcorcón,

C E R T I F I C A

Que este Comité ha evaluado la propuesta para que se realice el estudio **"Mapping Normative Frameworks for EThics and Integrity of Research (EnTIRE): Work Package 2 - Stakeholder Consultation"** y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.

El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.

Son adecuados tanto el procedimiento para obtener el consentimiento informado como la compensación prevista para los sujetos por daños que pudieran derivarse de su participación en el estudio.

El Investigador se compromete a responder a los informes de seguimiento que desde el CEIC se les requiera

Y que este Comité acepta que dicho estudio sea realizado por **D. Emanuele Valenti** como investigador principal.

Lo que firmo en Alcorcón, a 24 de julio de 2017.

Comité Ético de Investigación Clínica

Fdo.: Dra. Ana María Tato Ribera

Secretaria del CEIC del HUFA

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MEDICINSKI FAKULTET
SVEUČILIŠTA U SPLITU

Klasa: 003-08/17-03/0001
Ur. br.: 2181-198-03-04-17-0036

Etičko povjerenstvo

Split, 25. srpnja 2017.

MIŠLJENJE

Etičkog povjerenstva povodom prijave istraživanja:

Projekt H2020 „Mapiranje/Utvrđivanje normativnih okvira etike i istraživačke čestitosti“ ('Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE) ')

I. Zaprimljen je zahtjev prof. dr. sc. Ane Marušić za odobrenje znanstvenog istraživanja pod nazivom: **Projekt H2020 „Mapiranje/Utvrđivanje normativnih okvira etike i istraživačke čestitosti“ ('Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE)')** – provedba znanstvenog istraživanja na ljudima. Predviđeno je da ovo istraživanje započne u listopadu 2017. godine i da traje do 6 mjeseci, tj. do završetka svih fokus-grupa, a provodit će se na Medicinskom fakultetu Sveučilišta u Splitu te u VU University Medical Center u Amsterdamu. Glavni cilj ovog istraživanja je prikupiti informacije i iskustva pripadnika različitih interesnih skupina uključenih u istraživanja (istraživača, urednika časopisa, članova etičkih povjerenstava, donositelja prijedloga zakona, predstavnika industrije, uključujući farmaceutsku industriju, te predstavnika drugih izvora financiranja istraživanja) kako bi se odredio normativni okvir etike i istraživačke čestitosti.

II. Etičko povjerenstvo Medicinskog fakulteta Sveučilišta u Splitu je, prilikom raspravljanja o ovom predmetu, uzelo u obzir izjavu prijavitelja da rizika za ispitanike nema te da će potencijalna saznanja doprinijeti stvaranju mrežne stranice koja će informacije o etici i istraživačkoj čestitosti učiniti dostupnijima i jednostavnijima za korištenje. Također je uzeta u obzir izjava da će identitet ispitanika (zdravog ili pacijenta) uvijek ostati anoniman.

III. Sukladno odredbi članka 16. Etičkog kodeksa Medicinskog fakulteta u Splitu Povjerenstvo je zauzelo stajalište kako je predmetno istraživanje **u skladu s odredbama Etičkog kodeksa** koje reguliraju istraživanja na ljudima u znanstvenom, istraživačkom i stručnom radu i etičkim načelima Helsinške deklaracije.

IV. Mišljenje je doneseno jednoglasno.

Predsjednik Povjerenstva:

izv. prof. dr. sc. Marko Ljubković

Dostaviti:
- prof. dr. sc. Ana Marušić x2
- arhiv Etičkog povjerenstva Medicinskog fakulteta
- arhiv Fakulteta

Case, casuistry and scenarios (Work package 5)

The data collection work package ‘Cases, casuistry and scenarios’ will collect publically available information about published RE+RI cases. Some of these may contain identifying data, however this will be removed before being published on the online platform.