Mapping Normative Frameworks
of EThics and Integrity of Research

D3.1 Template for the collection of guidelines, codes, laws

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Template for the Collection of Guidelines, Codes and Laws

Deliverable D3.1
EnTIRE – Project 741782

Template for the collection of guidelines, codes, laws

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Introduction

In this document we will outline the main strategy we will follow for collecting guidelines, codes, legislations, and standards that have been created in the EU. After restating the scope and goals of work package WP3, we will give a first outline the general methodology in section 2. In subsequent sections we will give a preliminary list of the data that have been collected (section 3), a preliminary methodology for classifying the documents according to metadata (section 4), as well as some additional information on data management (section 5). In section 6 we include the template of the letter we will use to address research organizations (such as national research councils or bioethics committees), and in section 7 we will add a list of contacts with whom we will be conducting the pilot collection (for deliverable D3.2).

1. Recap of Scope and Goals of WP3

The work package will offer a detailed mapping and analysis of the normative documents on research ethics and research integrity that are available within the European Union. Our previously published overview of guidelines, standards, laws, and codes in European countries, regions and institutions[1] will be updated and extended, regarding the nature of the documents

[1] Mainly from the following two papers: (1) Bonn, N. A., Godecharle, S., & Dierickx, K. *Journal of Empirical Research on Human Research Ethics*, 12: 33-44 and (2) Godecharle, S., Nemery, B., &

to be included (research integrity, research ethics), regarding the level (national, regional, local, institutional), regarding the status (hard law, grey literature, etc.). The collection of data will be double checked by researchers and fellows in each EU country: the bodies that have drafted the normative documents as well as a network of national legal and scientific experts will be asked to check our findings. Also practical information on the interpretation and coordinates of the bodies that have drafted the normative frameworks will be gathered in coordination with WP4. Further on we will analyze and prepare the normative documents for integration in the wiki-platform of the project (e.g. distinction between legislation that must be applied and the soft laws and best practices that must be taken into account).

2. Method for Data Collection[2]

We will conduct a search of the documents on research integrity and research ethics, from all 27 countries of the European Union together with the four countries of the European Free Trade Association, i.e. Iceland, Liechtenstein, Norway, and Switzerland.

We will first focus on the documents related to scientific integrity, and once we have made sufficient progress on this front we will follow the same search methodology for documents related to research ethics.

To identify the relevant documents on scientific integrity, we will search Google, Google Scholar and PubMed. The searches will include searches for the following terms and their relevant combinations: “biomedical research”, “scientific misconduct”, “research misconduct”, “research ethics”, “scientific integrity”, “mentoring”, “education”, “biomedical research”, “mentor”, “training”, “bioethics”, “models of prevention”, “prevention of research misconduct”, “prevention”, “good scientific conduct”, “responsible conduct of research”, “disclosure”, “self-disclosure”, “guidelines”, “scientific fraud”, “fraudulent data”, “misconduct in science”, “questionable research”, “questionable research practice”, “fabrication”, “falsification”, “plagiarism”, “Europe”. We also will add the names of the individual European

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Dierickx, K. (2013). Guidance on research integrity: no union in Europe. *The Lancet*, 381: 1097-1098.

[2] The following methodology has been adapted from Godecharle S, Nemery B, Dierickx K (2013), and will be expanded and updated in the following two ways: EU countries which were missing from the first study (Bulgaria, Cyprus, Lithuania, Portugal, Romania, Slovenia, Luxembourg, Italy, Malta) will be added, and we will be updating the guidelines and codes, which may have been changed and revised substantially in the meantime.

countries.

The retrieved guidelines will be considered for possible inclusion if they have been published or explicitly referred to by one or more of the following national organizations: the bio-ethical committees listed by the World Health Organization (WHO), the national academies of sciences belonging to All European Academies (ALLEA), or a national research integrity organization, if any exist. This selection will ensure that the retrieved documents are in fact the ones of central importance for research in that country. In a second phase we will contact each of the aforementioned organisations by e-mail, and ask them if the guidelines we have found are indeed the relevant documents for their country. If we have been unable to find any guidelines, we will ask them whether guidelines existed concerning scientific integrity in their country. In a third phase we will also contact the national association of universities or an academic individual, such as someone who has published on scientific integrity or has spoken at previous edition of the World Conference on Research Integrity. We will also ask them to confirm whether the documents we have found or received are indeed relevant.

Finally, this methodology is subject to update as WP3 progresses, but also as the normative framework defined in the focus groups (WP2) develops (cf. task 3.2)

3. List of Collected Data

The following represents a provisional list of collected documents obtained through the methodology described avbove. This will be updated and extended as the work package WP3 progresses.

Country	Institution	Date of Publication	Document
LV	Latvian Academy of Sciences	1997	Scientist's Code of Ethics
DE	German Research Foundation	1998	Recommendations of the Commission on Professional Self- Regulation in Science
	German Council of Science and Humanities	2013	Proposals for Safeguarding Good Scientific Practice(First version: 1998)

	(Wissenschaftsrat)		
	German Council of Science and Humanities	2015	Recommendations on Academic Integrity: a position paper
FR	National Institute for Health and Medical Research	2000	Responding to Allegation of Scientific Misconduct: the Procedure at the French National Health and Medical Research Institute
	National Centre for Scientific Research	2006	Scientific fraud at the National Centre for Scientific Research
	National Alliance for Life and Health Sciences	2011	Recommendations for the signing of scientific papers in the field of life sciences and health
	French National Research Agency	2014	Politique en matière d'éthique et d'intégrité scientifique
	7 French Research Institutions (CIRAD, CNRS, CPU, INRA, INRIA, INSERM, IRD)	2015	French National Charter for Research Integrity
	French National Center for Scientific Research	2017	Integrity and responsibility in research practices: a guide
	French National Center for Scientific	2017	Ethical Reflection on Plagiarism in Scientific Research

	Research		
NL	Royal Netherlands Academy of Arts and Sciences	2001	Note on Scientific Integrity
	Royal Netherlands Academy of Arts and Sciences and All European Academies	2013	Memorandum on Scientific Integrity (First publication 2003)
	Association of Universities in the Netherlands	2014	The Netherlands Code of Conduct for Academic Practice (First publication 2004)
	Netherlands Research Foundation (NWO)	2013	NWO Fraud Protocol
	Netherlands Research Foundation (NWO)	2013	Regulation for Complaints about Scientific Integrity - granting
PL	Ministry of Science and Information Technology	2004	Good scientific research practice
	Polish Academy of Sciences	2001	Good manners in science. A set of principles and guidelines
EE	Estonian Academy of Sciences	2002	Code of Ethics for Estonian Scientists
FI	The National Advisory Board on Research Ethics	2002	Good scientific practice and procedures for handling misconduct and fraud in science

	The National Academy of Finland	2005	Guidelines on research ethics
UK	Wellcome Trust	2002	Guidelines on good research practice (updated in 2005)
	Wellcome Trust	2002	Statement on the handling of allegations of research misconduct (updated in 2005)
	Medical Research Council	2012	Good research practice: Principles and guidelines
	Medical Research Council	2014	Policy and Procedure for Investigating Allegations of Research Misconduct
	UK Research Integrity Office	2016	Good practice in research: Internet - mediated research
	UK Research Integrity Office	2016	Guidance for Researchers on Retractions in Academic Journals
	UK Research Integrity Office	2017	Good practice in research: Authorship
	UK Research Integrity Office	2014	Position statement on research involving security-sensitive material
	UK Research Integrity Office	2016	Position statement on the statutory regulation of research integrity
	UK Research Integrity Office	2008	Procedure for the investigation of misconduct in research
	UK Research Integrity Office	2009	Code of Practice for Research. Promoting good practice and preventing misconduct
	Universities UK	2012	The concordat to support research integrity
	Research Councils UK	2017	Policy and Guidelines on Governance of Good Research Conduct (first version 2012)
NO	Law	2006	Act of 30 June 2006 No. 56 on ethics and integrity in research

	The National Committee for Research Ethics in Science and Technology	2008	Guidelines for research ethics in science and technology
CZ	Academy of Sciences of the Czech Republic	2006	Code of Ethics for Researchers of the Academy of Sciences of the Czech Republic (additions made in 2010)
EL	Hellenic National Bioethics Commission	2008	National Commission of Bioethics. Opinion on research ethics in the biological science
	Hellenic National Bioethics Commission	2008	Report on research ethics in the biological sciences
	Hellenic National Bioethics Commission	2009	Template of Code of Research Ethics for Biological Sciences
	Hellenic National Bioethics Commission	2011	Opinion on conflict of interest in biomedical research
CH	Swiss Academies of Arts and Sciences	2008	Integrity in scientific research. Principles and procedures
BE	National Academy of Science	2009	Code of ethics for scientific research in Belgium
DK	Danish Committees on Scientific Dishonesty	2009	Guidelines for Good Scientific Practice
	Law	2009	Consolidated Act No 306
	Law		Consolidated Act No 1064

		2010	
	Ministry of Higher Education and Science (UFM)	2014	The Danish Code of Conduct for Research Integrity
HU	Hungarian Academy of Science	2010	Science Ethics Code of the Hungarian Academy of Sciences
IE	Health Research Board	2002	Disclosure and Conflict of Interest *(*
	Health Research Board	2008	HRB Guidelines for Host Institutions on Good Research Practice
	Health Research Board	2008	Policy for Dealing with Alleged Research Misconduct in Applications Made to the HRB
	Health Research Board	2008	HRB Guidelines for Host Institutions on the Handling of Allegations of Research Misconduct
	Irish Council for Bioethics	2010	Recommendations for promoting research integrity
	Royal Irish Academy	2010	Ensuring integrity in Irish research. A Discussion Document
	Health Research Board	2010	Health Research Board Position Statement on Authorship
	Health Research Board	2010	Details on how HRB Authorship position can be applied
	Irish Universities Association	2014	National policy statement on Ensuring Research Integrity in Ireland
AT	Austrian Agency for Research Integrity	2010	Rules of procedure for the investigation of alleged scientific misconduct
	Austrian Agency for	2010	Annex I to the Rules of Procedure of the Commission for Research Integrity: Guidelines for

	Research Integrity		the investigation of alleged scientific misconduct
	Austrian Agency for Research Integrity	2011	Statement of the Commission for Research Integrity on Handling Cases of Plagiarism
	Austrian Agency for Research Integrity	2015	Guidelines for Good Scientific Practice
ES	Spanish Bioethics Committee	2010	Recommendations of the Spanish Bioethics Committee in Relation to the Drive and Implementation of Good Scientific Practice in Spain
	Spanish National Research Council	2016	Good editorial practice guidelines for scientific journals and monograph series
	Spanish National Research Council	2015	Manual of Conflicts of Interest
	Spanish National Research Council	2015	National Statement on Scientific Integrity
SE	The Swedish Research Council	2004	Guidelines: Expert Group for Investigation of Suspected Research Misconduct
	The Swedish Research Council	2006	Conflict of interest policy
	The Swedish Research Council	2011	Good research practice

4. Methodology of Analysis

We plan on analyzing the documents (or data) on two fronts. The first will be to collect metadata on each document, and to organize the metadata in collaboration with IT partner GESINN.IT GMBH & CO. The second is to do a more thematic analysis of each document. The analysis will facilitate both the retrieval of information, as well as facilitate future research in research integrity by having a repository of basic analysis available.

A risk here is that the data collection will yield too many relevant documents, and that it will not be realistic with regard to workload to carry out an exhaustive analysis. In such a case, we will still carry out a representative analysis on the most important national and international guidelines, so that this representative analysis can be applied to other documents in the database by the users of the wiki platform.

A report on the analysis of the documents will be the subject of deliverable D3.3.

4.1 Methodology for Generating Metadata

We will generate metadata by assigning the following tags to each document. The following list is a provisional indication of the most important tags, but is subject to completion and updates as the work package progresses.

1. Name of Document
2. Issuing Country
3. Issuing Institute
4. Date of publication
5. Length of document
6. Web URL
7. Nature of Document (hard law, code, grey literature, etc.)

This list will be adjusted according to (1) input and suggestions from the IT partner GESINN.IT GMBH & CO, (2) needs of users once the platform is operational and there is a user feedback channel in place.

4.2 Methodology for Generating Content Analysis

For the initial set-up of the wiki platform, we plan on carrying out an initial content analysis of the documents, or, depending on the quantity of documents and the feasibility, at least a substantial number of them. This preliminary content analysis subsequently can be updated and completed by the users according to the rules of the wiki platform.

Based on the methodology of content analysis described by Elo and Kyngäs[3] (2008) and on previous research[4] (Bonn, Godecharle, and Dierickx 2017), the following list is the result of a provisional content analysis. The list represents a provisional list of the general themes, principles of integrity, and types of misconduct that are mentioned or discussed across multiple guidelines at LERU universities.

To improve on this provisional result, we plan on carrying out the following steps:

1. We will update this list, increase consistency, and where needed, detail.
2. We will then apply it to EU guidelines at national and international level concerning research integrity and research ethics.
3. We will carry out a preliminary statistical analysis on the relative frequencies of the content categories.

This will be carried out in months 15-38 of the EnTIRE project, and is subject for deliverable D3.3.

4.2.1 General Themes

The following types of theme frequently are mentioned or discussed across guidelines, here grouped into the 5 categories concerning data practices, research process, human participants, publication and dissemination, and peer review.

Data Practices:

(1) Storage
(2) Archive
(3) Access
(4) Disposal

Research Process:

(1) Adhere to ethical and legal obligations
(2) Funding (incl. conflicts of interest)
(3) Allow for audit and replication
(4) Training
(5) Careful design and methods
(6) Health, safety, and welfare

[3] Elo, S., & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of advanced nursing*, *62*(1), 107-115.

[4] Aubert Bonn, N., Godecharle, S., & Dierickx, K. (2017). European Universities' Guidance on Research Integrity and Misconduct: Accessibility, Approaches, and Content. *Journal of empirical research on human research ethics*, *12*(1), 33-44.

(7) International collaboration
(8) Respect for environment
(9) Give due credit

Human participants:
(1) Respect and care
(2) Confidentiality
(3) Informed consent

Publication and Dissemination:
(1) Authorship
(2) Report conflicts of interest
(3) Avoid plagiarism; give due credit
(4) Intellectual property
(5) Acknowledgements
(6) Publish in a timely manner
(7) Publish access and open access
(8) Avoid duplication or salami slicing

Peer review:
(1) conflicts of interest
(2) confidentiality
(3) Plagiarism

4.2.2 Principles of Integrity

The following list represents the virtues and principles of integrity that are mentioned or discussed most frequently across guidelines.

(1) Openness and verifiability
(2) Excellence; rigor; meticulousness
(3) Objectivity; scrupulousness; transparency
(4) Honesty; veracity
(5) Independence; selflessness
(6) Responsibility of future generations
(7) Integrity
(8) Cooperation; solidarity; collaboration
(9) Reliability; accuracy
(10) Accountability; responsibility
(11) Respect of rules, laws, and standards
(12) Impartiality

(13) Social responsibility; Commitment
(14) Freedom of research and/or teaching
(15) Fairness; Give due credit to others
(16) Avoid and prevent misconduct
(17) Ambition; innovation; inspiration

4.2.3 Types of Misconduct

The following list represents the types of misconduct that are mentioned or discussed most frequently across guidelines.

(1) Plagiarism
(2) Fabrication
(3) Falsification
(4) Misrepresentation/deception
(5) Selective reporting
(6) Bad authorship practices
(7) Disclose unpublished research/ breach confidentiality
(8) Facilitating misconduct of others
(9) Failure to report conflicts of interest
(10) Inadequate preservation/availability of data
(11) Failure to meet ethical/legal requirements
(12) Breach of duty of care
(13) Concealing misconduct of others
(14) Interference with research activities of others
(15) Neglect of supervisory duties
(16) Improper dealing with misconduct
(17) Infringements against whistleblower
(18) Malicious accusation of misconduct
(19) Duplicate publication

5. Accessibility, Interoperability, Re-use, and Preservation of Data

All the data are text files and are part of the public domain. Due to their format, there are no foreseen potential problems regarding interoperability. Furthermore, since they are publically available, they will remain freely accessible, freely reusable, and preserved.

The URL addresses of documents are changed at a more rapid rate than the documents (they can change each time the website of the national research agency is updated). Therefore we will upload the documents directly to the wiki platform, as well as provide the URL links. This

will maximize access to the documents, and allow (through web search) the new URL link to be retrieved. This will help minimize the effort involved to keep the wiki platform up-to-date.

6. Letter Template

The following represents the letter template we will be using to contact representatives of European research organizations. The purpose of the letter is to verify that the documents we have added to our database are authentic, up to date, and complete. The text within <> will be adjusted according to the addressee.

This template is provisional, and may be adjusted according to further developments in the project, as well as in response to feedback we get as we start to send out these letters.

> Dear <Dr. John Doe>,
>
> We are writing to you on behalf of the European Research Project 'EnTIRE' (http://entireconsortium.eu).
>
> We are tasked with collecting guidelines and regulations on research ethics and research integrity in the European Union.
>
> It is crucial for the success of our project that we conduct a minimal verification of the documents we have added to our database.
>
> We therefore ask you if you would be so kind as to verify (for the record) that the following documents are (1) authentic, (2) up to date, and (3) that we have not missed important documents on research <ethics/integrity>[5].
>
> In particular, for <Sweden> we have added the following documents:
>
> 1. "<**Good Research Practice**>",
>   version of <**November 2011**>
>   (URL:<https://www.vr.se/download/18.3a36c20d133af0c1295800030/1340207445948/Good+Research+Practice+3.2011_webb.pdf>)
> 2. **"<The Swedish Research Council's Expert Group for Investigation of Suspected Research Misconduct>"**,
>   version of **29 September 2004**
>   (URL:
>   https://www.vr.se/download/18.6a9398491107cea06a580001887/Expert+Group+for+Investigation+of+Suspected+Research+Misconduct.pdf)

[5] Note: some organizations specialize only in research ethics, others only in integrity, and some in both, so this will need to be adjusted according to addressee.

3. "<Conflict of Interest Policy>",
   Version of <**28 February 2006>**
   (URL:
   https://www.vr.se/download/18.aad30e310abcb973578000266/1340207441717/Conflict_of_interest_policy.pdf)

We had a question regarding the <Conflict of Interest Policy>, which seems to exist in at least three versions. Besides the one pasted above, there is a 2014 version (URL: https://www.vr.se/download/18.395547dd14a09cd1891383cc/1417531906343/Conflict+of+Intereste_april2014.pdf), as well as a 2001 version which is referred to in the 2006 document, but of which we cannot find an online version. We included in the 2006 version over the 2014 version because it seemed to be more complete. Are we justified in leaving the 2001 and 2014 version out of our database?[6]

Besides that specific question, we would be very grateful if you could verify, for the record, that these are authentic and the latest versions. We would be grateful to pointers to important documents we may have missed, and otherwise would also be grateful if you can state, again for the record, that this list is the complete list of relevant documents on research <ethics/integrity> <at your institution/in your country>.

Feel free to respond in-line if convenient.

We sincerely thank you for your time and effort.

Yours truly,

Prof. Dr. Kris Dierickx
Dr. Hugh Desmond

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Full Professor / *Gewoon Hoogleraar*
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[6] This paragraph is optional, and may be left out if we do not have any specific questions for the representative of the research institution.

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7. Contacts for Pilot Collection

The following list contains the contact details of the persons we will be collaborating with for the planned pilot searches in Croatia and Spain.

1. Name: Ana Marušić

   Organization: Sveuciliste u Splitu Medicinski Fakultet

   Email: ana.marusic@mefst.hr
2. Name: Emanuele Valenti Benjamin

   Organization: Universidad Europea de Madrid

   Email: emanuele.valenti@universidadeuropea.es