SOPs4RI

D3.1: Protocol for the literature review, the expert interviews and the Delphi procedure

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D3.1: Protocol for the literature review, the expert interviews and the Delphi procedure

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1. Introduction

1.1 Abbreviations

RI – Research Integrity

SOP – Standard operating procedure

RPO – Research performing organisation

RFO – Research funding organisation

RIPP – Research Integrity Promotion Plan

ECoC – European Code of Conduct

1.2 Terminology

Code: a document guiding the members of an organisation on ethical standards and how to achieve them.

Ethics/integrity codes are formal documents sending a message about moral standards guiding professional behaviour by providing principles, values, standards, or rules of behaviour.

Guideline: a statement of principles or issues to consider when performing a task, aimed to guide courses of action.

Guidelines give direction and help users make decisions. They are often created based on the consensus of experts after detailed evaluation and assessment of available scientific evidence. They may include checklists.

Standard Operating Procedure (SOP): a detailed, written instruction, aimed to achieve uniform action step-by-step.

SOPs prescribe specific actions; they liberate users from decision-taking by ensuring that the procedure is followed. They may come in the shape of a 'decision-tree'/flow-diagram, similar to what is referred to as an algorithm in clinical contexts.

Toolbox: a structured collection of easy-to-use SOPs and guidelines that RPOs and RFOs can use when developing their own Research Integrity Promotion Plans.

Research Integrity Promotion Plan (RIPP): a document describing how a specific institution will ensure, foster and promote responsible research practices, avoid detrimental practices, and handle misconduct.

It is the intention that RPOs and RFOs should form their own RIPPs in order for them to take disciplinary, organisational and national differences into account.

1.3 About SOPs4RI

The Standard Operating Procedures for Research Integrity (SOPs4RI) project aims to contribute to the promotion of excellent research and a strong research integrity culture aligned with the principles and norms of the European Code of Conduct for Research Integrity. The overall objective is to create a toolbox to support and guide research performing organisations (RPOs) and research funding organisations (RFOs) in fostering research integrity and consequently preventing, detecting and handling research misconduct. The project focuses on providing Standard Operating Procedures (SOPs) and guidelines that will make it possible for RPOs and RFOs to create and implement Research Integrity Promotion Plans (RIPPs). SOPs4RI will thus stimulate transformational processes across European organisations involved in doing and funding research. SOPs4RI takes a mixed-methods, co-creative approach to the development and empirical validation of SOPs and guidelines.

The expected end-users of the tools provided by SOPs4RI are decision makers within RPOs and RFOs, e.g. university senior management (vice chancellors, deans, heads of administration), university academic councils, boards and directors of funding agencies, and their extended administrations. The development of SOPs and guidelines will take national, epistemic, and organisational differences into account, and the final toolbox will enable end-users to create Research Integrity Promotion Plans in accordance with the needs of their organisation.

1.4 About WP3 – Systematic review of practices and research cultures

In order to develop a toolbox to support RFOs and RFOs in fostering research integrity and preventing, detecting and handling research misconduct, it is necessary to develop the evidence base regarding the factors that have a positive or negative influence on the implementation of research integrity in RFOs and RPOs. Work Package (WP) 3 in the project will contribute to this objective by conducting scoping reviews of the existing evidence, expert interviews, and a Delphi survey aimed at identifying the most important topics to address when developing SOPs and guidelines.

To be able to develop a toolbox with SOPs and guidelines applicable across different academic disciplines and institutions, it is important to explore existing practices relevant for different levels of implementation. Hence, WP3 will broadly examine existing practices related to fostering research integrity and avoiding and handling misconduct, and explore how these relate to research culture.

The following components are part of WP3:

- Literature review and modelling research cultures

As a starting point, a comprehensive literature search will be conducted. The protocols for conducting literature search are presented later in the document. To explore all knowledge relevant for the aim of the SOPs4RI project two scoping reviews, regarding best practices for research integrity promotion in RPOs and RFOs and factors influencing implementation of those practices, will be conducted.

In parallel to the literature review, the first task includes the development of a framework to model the culture of research systems in different disciplines. The developed framework will contribute to a better understanding of the impact of research culture on researchers and research integrity.

- Expert interviews

The knowledge identified through the literature review will be further explored in interviews with research integrity experts. The interviews will include stakeholders with different roles regarding research integrity.

- Delphi survey study

Based on an iterative consensus process among experts in research integrity issues at RPOs and RFOs, the Delphi survey will identify the most important topics to be covered by the toolbox.

1.5 About this deliverable

Deliverable 3.1 provides protocols for the following studies, all of which are part of WP3:

- Scoping review on 'Best practices for research integrity promotion in research performing and research funding organisations';
- Scoping review on 'Factors influencing implementation of practices for research integrity promotion in research performing organisations and research funding organisations';
- Expert interviews;
- Delphi procedure.

2. Best practices for research integrity promotion in research performing and research funding organisations: a scoping review protocol

2.1 Introduction

Research integrity represents the base for the advancement of knowledge and science (1). Although there is no universally accepted definition of research integrity, it is generally considered to refer to performing research in accordance with the highest level of professionalism and ethical standards (2). For example, in Europe, major and minor violations of research integrity, as well as norms for responsible research behaviour, are listed in the European Code of Conduct for Research Integrity. Therefore, researchers, research performing organisations (RPOs), and research funding organisations (RFOs) across Europe are all responsible for the implementation of the European Code of Conduct (3).

Researchers agree that fabrication, falsification, and plagiarism represent violations of research integrity, but their opinions differ when it comes to more frequent, minor breaches of research integrity (4). Examples of the latter are mentioned in the European Code of Conduct and include authorship manipulation, selective citing, re-publishment of substantive parts of one's earlier publication, withholding of research results, misrepresentation of research achievements, and establishing 'predatory journals' (3). Moreover, serious violations of research integrity, i.e. fabrication, falsification, and plagiarism (FFP), are relatively rare (5), while other breaches are more prevalent and therefore it is both necessary and important to regulate them (4). Some of the reasons that explain more frequent occurrence of minor research integrity breaches include the lack of explicit definitions about what type of behaviour is considered a violation of RI, i.e. what is considered to be a questionable research practice (QRP), as well as the lack of uniformity with regard to codes and guidelines among different institutions (1,4). Moreover, some questionable research practices (QRP) are identified as being explicit violations of research integrity and are named 'detrimental research practices' (6). All these factors, both at a personal and at the institutional level, contribute to the problem of research waste and continue to diminish the society's trust in science. RPOs and RFOs have an important role in promoting research integrity since the researchers and their host institutions (7) hold

the responsibility for research results. Hence, institutions should contribute to better science and foster trust in science by implementing policies for the promotion of research integrity (7).

This review seeks to identify existing documents and practices for research integrity promotion in RPOs and RFOs. The aim is to gather knowledge about best practices that can be implemented in RPOs and RFOs in alignment with the European Code of Conduct for Research Integrity. Subsequently, the implementation of those practices by RPOs and RFOs will provide researchers with better guidance regarding adherence to research integrity and fostering trust in science.

2.2 Review question/objective

The objective of this review is to identify best practices that can be implemented in RPOs and RFOs with the aim of promoting research integrity among all scientific disciplines and ensuring high-quality science.

Review questions are as follows:

- Which practices and standardised approaches for promoting research integrity and avoiding research misconduct exist in research performing organisations?
- Which practices and standardised approaches for promoting research integrity and avoiding research misconduct exist in research funding organisations?

2.3 Methods

For the literature review, we will follow the methodology and guidance for the conduct of scoping reviews published in the Joanna Briggs Institute (JBI) Review's Manual (8). The first step will include an initial limited search of relevant databases, followed by an analysis of the text words contained in the titles and the abstracts, and of the index terms used to describe the articles (9).

2.4 Data sources

In this scoping review, the 'population' is literature related to research integrity practices for RPOs and RFOs in different scientific fields. These practices include any professional rules related to research integrity (SOPs, guidelines, codes of conduct, charters, and checklists) as well as training and education for research integrity and procedures to deal with research misconduct.

2.5 Concept

The concept of this review is that there are existing professional rules and practices with implications on research integrity (RI) promotion, i.e. RI education, establishment of RI committees and offices, procedures to deal with research misconduct, data management, principles for open science and open innovation, protection of whistle-blowers, and a responsible reward system.

2.6 Context

This scoping review will examine the existing literature related to practices for research integrity, within all fields of science and within different organisations (RPOs and RFOs) involved in research.

2.7 Search strategy

The literature search will be comprehensive, including both peer-reviewed publications and grey literature. The European Code of Conduct will be taken as a starting point, with its terms and definitions serving as the basis for the development of the search strategy. The search strategy will be designed and implemented in cooperation with an experienced librarian (AU) from the University of Split, School of Medicine. Because of the complexity of the terminology related to the review topic, the search strategy will aim at high sensitivity rather than specificity and will include a wide approach to the field. Such sensitive and wide strategy will be adequate for both scoping reviews planned in the SOPs4RI project. Articles related to the topic of the first scoping review will be identified

through a systematic search of bibliographical databases, whereas the grey literature search will be performed through specialized databases.

Bibliographical databases that will be searched include *Scopus*, *Web of Science* (WoS), *PubMed*, and *PsychINFO*. The search strategy is presented in Appendix A.

We will also search the *OpenGrey* database for grey literature. Grey literature search will include abstracts from the World Conferences on Research Integrity (WCRI) which will be identified through the conference web pages (https://wcrif.org/). Further, the search will also include a database of European projects related to research integrity to identify materials developed by those projects (https://cordis.europa.eu/projects/home_en.html).

2.8 Inclusion and exclusion criteria

The results will include materials that are explicitly related to the practices for research integrity promotion in RPOs and RFOs (articles, codes of conducts, guidelines, standard operating procedures, legal documents, policies, charters, checklists). There will be no geographical restrictions as we will also include non-European research integrity developments.

The literature search will be limited to materials written in English because of an expected large number of retrieved documents. Since research misconduct emerged as a serious problem in the late 1980s and in 1990s (6), our results will be limited to those published after 1990, considering the later development of the research integrity concept and field, as well as to ensure applicability and contemporaneity of retrieved materials.

2.9 Study selection

For a more systematic approach and to avoid duplication, data collection will be carried out using the EndNote tool. All materials will be assessed by two independent reviewers (RS and IB) that will be joined by the third reviewer (AM) in the final decision-making process. Both assessors need to agree in order for the materials be included in the final results. In the case of disagreement, the third reviewer's (AM) opinion will contribute to

reaching the final decision. The second screening, i.e. screening of excluded materials will be assessed by a reviewer from STICHTING VUMC (KL).

The study selection will also include a screening of the reference lists of all included articles for the identification of additional studies (9).

2.9.1 Contribution of WP partners

The assessment of the included materials, and study selection process for this scoping review, will include collaboration between WP partners as presented in the section *Study selection*. The research group members are listed in the table below.

Table 1. The research group members for the literature review: Best practices for research integrity promotion in RPOs and RFOs

WP partner	*Contributors*
MEFST	Rea Ščepanović, Ivan Buljan, Ana Marušić
STICHTING VUMC	Krishma Labib, Joeri Tijdink

2.10 Data extraction

Documents will be mapped in the table with the following categories:

- title of the document;
- author(s);
- type of the document;
- field of science (Humanities, Social science, Natural science - including engineering, and Medical science - including biomedicine);
- whether the document is more related to RPOs or RFOs or equally;
- whether the document considers more professional rules such as codes of conduct, SOPs, and guidelines or practices (education, training, etc.);

- specificity of the materials (informative/descriptive, interactive materials, research materials);
- Empirically grounded (Y/N), and if YES then link.

2.11 Data analysis and presentation

The results will be reported in narrative form in accordance with the PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist (10). Moreover, the process of identification, screening and inclusion of studies will be presented in the PRISMA flow diagram for the scoping review process, presented in the **Appendix B**. Since the risk of bias across studies is not applicable for scoping reviews (10), the retrieved materials will not be evaluated for the risk of bias.

Overview of the relevant European projects on research integrity, which will be identified through the search of the CORDIS database, will be presented in the table with additional information and specification of retrieved materials.

2.12 Expected outputs

The expected outputs of this study include 1) this scoping protocol review, 2) scoping review (deliverable D3.2) and 3) published review.

2.13 References

1. Aubert Bonn N, Godecharle S, Dierickx K. European Universities' Guidance on research integrity and misconduct. J Empir Res Hum Res Ethics. 2017;12(1):33-44.
2. Science Europe. Research Integrity Practices in Science Europe Member Organisations. Survey Report. July 2016; http://www.scienceeurope.org/wp-content/uploads/2016/07/Scienc Europe Integrity Survey Report July 2016 FINAL.pdf . Last retrieved 19 Nov 2018.
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4. Bouter LM, Tijadink J, Axelsen N, Martinson BC, Gerben ter R. Ranking major and minor research misbehaviours: results from a survey among participants of four World Conferences on Research Integrity. BioMed Central. 2016;1:17.
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7. Begley CG, Ioannidis JP. Reproducibility in science "Improving the standard for basic and preclinical research". Circ Res. 2015;116:116-126.
8. Peters MDJ, Godfrey CM, McInerney P, Soares CB, Khalil H, Parker D. Methodology for JBI scoping reviews. The Joanna Briggs Institute Reviewers' Manual 2015. Adelaide, South Australia: The Joanna Briggs Institute; 2015.
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10. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and explanation. Ann Intern Med. 2018;169:467-473.

3. Factors influencing implementation of practices for research integrity promotion in research performing organisations and research funding organisations: a scoping review protocol

3.1 Introduction

Research integrity represents the base for the advancement of knowledge and science (1). Although there is no universally accepted definition of research integrity, it is generally considered to refer to performing research in accordance with the highest level of professionalism and ethical standards (2). For example, in Europe, major and minor violations of research integrity, as well as norms for responsible research behaviour, are listed in the European Code of Conduct for Research Integrity. Therefore, researchers, research performing organisations (RPOs), and research funding organisations (RFOs) across Europe are all responsible for the implementation of the European Code of Conduct (3).

Researchers agree that fabrication, falsification, and plagiarism represent violations of research integrity, but their opinions differ when it comes to more frequent, minor breaches of research integrity (4). Examples of the latter are mentioned in the European Code of Conduct and include authorship manipulation, selective citing, re-publishment of substantive parts of one's earlier publication, withholding of research results, misrepresentation of research achievements, and establishing 'predatory journals' (3). Moreover, serious violations of research integrity, i.e. fabrication, falsification, and plagiarism (FFP), are relatively rare (5), while other breaches are more prevalent and therefore it is both necessary and important to regulate them (4).

To identify factors influencing the implementation of practices for research integrity promotion, it is important to observe a currently existing research culture and take into account everyone involved in research, including researchers, supervisors, managers, research integrity professionals, funders, journal editors, and reviewers. Individual researcher's behaviour is affected by the institutional culture and funding system, therefore, RPOS and RFOs have an important role in promoting research integrity since the researchers and their host institutions (6) hold responsibility for research results. Hence,

institutions should contribute to better science and foster trust in science by implementing policies for the promotion of research integrity (6) and the implementation of research integrity policies alone should be further explored and developed.

This review will focus on the experiences of RPOs and RFOs with regard to the implementation of standard operating procedures (SOPs), guidelines and codes for the promotion of research integrity. This will provide information about which practices for research integrity should be implemented in the research organisations, what are the institutional obstacles for their implementation as well as benefits of implementation regarding research, science and society. Moreover, the review will seek to identify prominent elements in research culture that may influence the implementation of best practices for research integrity promotion within research organisations.

3.2 Review question/objective

The aim of this review is to examine factors influencing the implementation of best practices for research integrity promotion within RPOs and RFOs.

Specifically, the review questions are:

- What are the factors influencing the implementation of practices for research integrity promotion in research performing organisations and research funding organisations?
- In which way are research integrity policies related to other institutional and research policies?
- How do integrity policies fit into research cultures?[2]

3.3 Methods

In this scoping review, we will follow the methodology and guidance for the conduct of scoping reviews published in the Joanna Briggs Institute (JBI) Review's Manual (7). The first

[2] For example, research culture in this context refers to factors as overall quality assurance/peer review system, trends in research funding, national science and research integrity policies, and science culture often captured in diagnoses like 'academic capitalism', 'publish or perish-culture', 'accelerated academies', 'mode II' etc.

step will include an initial limited search of relevant databases, followed by an analysis of the text words contained in the titles and the abstracts, and of the index terms used to describe the articles (8).

3.4 Data sources

In this scoping review, the 'population' is literature on factors, related to research institutions or research culture elements, influencing implementation of research integrity practices in RPOs and RFOs in different fields of science.

3.5 Concept

The concept of this review are any factors (e.g. institutional rules and elements in research culture) that have an influence on the implementation of practices for the promotion of research integrity in RPOs and RFOs.

3.6 Context

This scoping review will examine existing literature within all fields of science related to positive and negative factors influencing the implementation of research integrity practices. This includes elements within research culture that may have an impact on the implementation of best research integrity practices in RPOs and RFOs, as well as other influence regarding the publishing of the research findings, funding opportunities and career advancement.

3.7 Search strategy

The European Code of Conduct will be taken as a starting point, with its terms and definitions serving as the basis for the development of the search strategy. The literature search will include both peer-reviewed publications and grey literature. The search strategy is designed and implemented in cooperation with an experienced librarian (AU) from the University of Split, School of Medicine. The search strategy, that will be the same as for Protocol 1, is presented in Appendix A.

Bibliographical databases that will be searched include *Scopus*, *Web of Science* (WoS), *PubMed*, and *PsychINFO*. We will also search the *OpenGrey* database for grey literature. Grey literature search will include abstracts from the World Conferences on Research Integrity (WCRI) which will be identified through the conference web pages

(https://wcrif.org/). Further, the search will also include a database of European projects related to research integrity to identify materials developed by those projects (https://cordis.europa.eu/projects/home_en.html).

3.8 Inclusion and exclusion criteria

The research culture, in general, will not be explored, meaning the focus will be on the elements of the research culture that may influence the implementation of practices for the research integrity promotion. Hence, the inclusion criteria will pertain to the influence of research institutions policies, funding institutions policies, journals policies and other policies related to the researcher's career perspectives. The search strategy will not have any geographical restrictions but it will be limited to materials written in English due to the expected large number of retrieved documents. For the grey literature search, we will use sensitive terms 'research AND integrity'.

Since research misconduct emerged as a considerable problem in the late 1980s and 1990s (9), we will limit our results to those published after 1990 due to the later development of the research integrity concept and field, as well as to ensure applicability and contemporaneity of retrieved materials.

3.9 Study selection

For a more systematic approach and to avoid duplication, data collection will be carried out using the EndNote tool. All materials will be assessed by two independent reviewers (RS and IB) that will be joined by the third reviewer (AM) in the final decision-making process. The reviewers will examine the relevance and quality of the retrieved materials. Both assessors need to agree in order for the materials be included in the final results. In the case of disagreement, the third reviewer's (AM) opinion will contribute to reaching the final decision. The results will include literature related to the factors, elements of research culture and experiences of research institutions influencing implementation of RI promotion practices within RPOs and RFOs. For example, this will include materials concerning the award system, the pressure to publish, researchers career perspectives, the pressure to obtain fundings, the behaviour of supervisor and peers. Since those factors may incentive research misconduct, we will also include materials concerning why researchers involve in research misconduct. The study selection will also include a screening of the reference lists of all included articles for the identification of additional studies (8). The

second screening, i.e. screening of excluded materials will be assessed by reviewers from the University Leiden (ARE and WK).

3.10 Contribution of WP partners

The assessment of the included materials, and study selection process for this scoping review, will include collaboration between WP partners as it is presented in the section *Study selection*. The research group members are listed in the table below.

Table 2. The research group members for the literature review: Factors influencing implementation of practices for research integrity promotion in RPOs and RFOs

WP partner	*Contributors*
MEFST	Rea Ščepanović, Ivan Buljan, Ana Marušić
CWTS	Andrea Reyes Elizondo, Wolfgang Kaltenbrunner

3.11 Data extraction

Documents will be mapped in the table with the following categories:

- title;
- author(s);
- type of the document;
- field of science (Humanities, Social science, Natural science, including engineering and Life science, including biomedicine);
- whether the document is more related to RPOs or RFOs, or equally;
- whether the document addresses positive or negative factors that influence implementation of RI promotion practices;
- whether the document focuses more on research culture or institutional positive/negative influence, specificity of materials (informative/descriptive, interactive materials, research materials);

- Empirically grounded (Y/N), and if YES then link.

3.12 Data presentation

The results will be reported in narrative form in accordance with the PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist (10). Moreover, the process of identification, screening and inclusion of studies will be presented in the PRISMA flow diagram for the scoping review process, as shown in **Appendix B**. Since the risk of bias across studies is not applicable for scoping reviews (10), the retrieved materials will not be evaluated for the risk of bias. Overview of the relevant European projects on research integrity, which will be identified through the search of the CORDIS database, will be presented in the table with additional information and specification of retrieved materials.

3.13 Expected outputs

The expected outputs of this study include 1) this scoping protocol review, 2) scoping review (deliverable D3.2) and 3) published review.

3.14 References

1. Aubert Bonn N, Godecharle S, Dierickx K. European Universities' Guidance on research integrity and misconduct. J Empir Res Hum Res Ethics. 2017;12:33-44.
2. Science Europe. Research Integrity Practices in Science Europe Member Organisations. Survey Report. July 2016; http://www.scienceeurope.org/wp-content/uploads/2016/07/Science-_Europe_Integrity_Survey_Report_July_2016_FINAL.pdf. Last retrieved 19 Nov 2018.
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4. Protocol for the expert interviews

4.1 Rationale

Among existing professional rules and practices for responsible research conduct, researchers have difficulties identifying best practices for avoiding research misconduct (1). Hence, for the promotion and fostering research integrity (RI) in science, the best practices for research integrity should be embedded in research performing organizations (RPOs) and research funding organizations (RFOs) as codes of conduct, guidelines, and standard operating procedures (SOPs). Moreover, to understand why researchers engage in research misconduct it is important to explore the elements of a research culture that may influence the implementation of professional rules and practices for research integrity promotion (2). This can also help in identifying in which way research culture may incentivise research misconduct as well as address necessary changes for the improvement of the research culture (3).

The Standard Operating Procedures for Research Integrity (SOPs4RI) project aims to collect existing standard operating procedures and guidelines and to develop them further for the implementation in research performing organisations and research funding organisations across Europe. SOPs4RI will create an online toolbox taking into account differences between disciplines and countries. The toolbox will present key elements, i.e. standard operating procedures and guidelines, which will help research performing organisations and research funding organisations create their own institution-tailored Research Integrity Promotion Plans (RIPP).

4.2 Aim

To create a toolbox of standard operating procedures and guidelines for Research Integrity Promotion Plans it is important to gain a better understanding of existing professional rules, practices, and factors influencing their implementation.

This protocol concerns expert interviews which will provide additional knowledge on general elements for fostering research integrity in RPOs and RFOs. Taken together, the literature search and expert interviews will further be used as a basis for the toolbox,

consisting of standard operating procedures and guidelines, which can be applied among different academic disciplines.

In conducting interviews, the focus will be on identifying novel and innovative SOPs that were not documented in the previously conducted literature search, as well as to identify prominent institutional and research culture elements important for the further development of SOPs, guidelines, and research integrity among different scientific disciplines.

4.3 Study design

To identify key elements for the toolbox, a qualitative approach will be used and face-to-face interviews will be conducted with research integrity experts from different scientific fields and different area of expertise (researchers, members of RI committees, funding organisations, policy makers, and industry).

In this context, an expert is a person who has relevant education on research integrity as well as significant practical experience working in the field of research integrity.

The aim is to conduct a total of 20 interviews. In the case of expressed interest by a greater number of RI experts during the recruitment process, additional interviews will be carried out.

Conducting face-to-face expert interviews will provide insight into experts' opinions on professional rules and tools for the promotion of research integrity. It aims to identify best practices that can be implemented within research institutions. This will lead to mapping and development of the most important SOPs and guidelines in the field of RI.

Interviews will explore the essential elements of SOPs and guidelines, why researchers engage in research misconduct, in which way institutions contribute to research misconduct, what the other factors are (e.g. research culture elements) influencing violations of research integrity and in which ways research performing organisations and research funding organisations can counter major and minor violations of research integrity.

In order to gain detailed insight into expert experiences about these questions, the interviews will be semi-structured. The predefined questions will be updated with

additional ones, since important questions may arise during the interview process (4). This will be done after the analysis of the first five conducted interviews.

Since experts' opinions regarding SOPs and guidelines play a major role in building the basis for the further development of the project and contribute to its success, it is important to note all the information provided by research integrity experts in the interviews. Thus, the interviews will be voice-recorded.

The voice records will be used only for the purposes of the SOPs4RI project, i.e. for the development of the toolbox for the RIPPs in RPOs and RFOs. The recorded conversations will be transcribed and, after conducting all interviews, analysed using the software for qualitative text analysis (NVivo, QSR International) with thematic analysis method (5).

The collection and management of data will be performed according to the Data Management Plan of the project (deliverable D1.2).

4.4 Study population and sample size

At least 20 stakeholders will be recruited to participate in the interviews. The participants will be recruited from different areas as follows: research, education (n=4), RI committees (n=4), funding and process organisations (n=4), policy-makers (n=4), industry (n=4).

The aim is to include stakeholders across different scientific fields as well as stakeholders from different European countries to ensure a diversity of experiences and suggestions. The recruitment strategy is presented further in the protocol.

4.5 Inclusion criteria and exclusion criteria

Eligibility for participating in interviews will include:

- Experts in the field of RI

For recruitment purposes, we define an expert as a person who has relevant education in research integrity and practical experience working in the field of research integrity (6). For different types of stakeholders, the criteria to consider are:

- researcher/educator: experience in scientific research (any scientific discipline) supported by published articles in the field of RI; experience in teaching or training in the field of RI,
- member of the RI committee: local or national RI committee; experience in teaching or training in the field of RI; participation in handling the cases of research misconduct,
- funding and process organisations: knowledge and experience in the field of RI; participation in the institutional project assessment and decision-making bodies,
- policy-makers: journal editors with knowledge and experience in the field of RI; members of the policy-making/decision-making body within the research institution; members of the national bodies with experience in developing legal acts, codes, and policies,
- industry: experience in working with research institutions on RI issues;

- participation and experience in developing codes of conduct, guidelines or SOPs for RI;
- published articles or other documents in the field of RI;
- participation in EU projects centred around RI.

The participants do not have to meet all of the above criteria but at least one.

4.6 Recruitment strategy

For participation in the interview, experts will be identified through several sources, as follows:

- European Network of Research Integrity Offices - ENRIO[3];
- European Ethics and Research Integrity Network – ENERI[4];

[3] http://www.enrio.eu/

[4] http://eneri.eu/

- Mutual Learning Exercise on Research Integrity – MLE on RI[5];
- European Network of Research Ethics Committees – EURECNET[6].

We will also use personal contacts and the project consortium for recruitment, including the Advisory Board. The 'snowball sampling' technique will be used to identify more potential participants (7).

The eligibility for participation in the interviews, conducted by WP leader (MEFST), will be assessed by two researchers (RS and IB) and in cases of disagreement, the third researcher (AM) will mediate the final consensus. The eligibility for participation in the interviews, conducted by the WP partners (as presented in the section *Contribution of WP partners*) will be assessed by researchers of the WP partners in accordance with the eligibility criteria presented in the document.

The participants will receive the invitation letter that will present the aims and objectives of the SOPs4RI project, together with the details of the participation in the interview. The consent form, which must be signed in order to participate in the interview, will be sent together with the invitation letter. The templates of the invitation letter/information sheet and informed consent form are presented in Appendix C. The invitation letter will clearly address the data protection procedures in alignment with the European Union Law, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data – General Data Protection Regulation (applicable as of 25 May 2018 in all European Union member states) and Danish Ministry of Higher Education and Science's recommendation in the Danish Code of Conduct for Research Integrity - Section II. 2. 1. i.[7]

5 https://rio.jrc.ec.europa.eu/en/policy-support-facility/mle-research-integrity

6 http://www.eurecnet.org/index.html

7 Can be found at: https://ufm.dk/en/publications/2014/the-danish-code-of-conduct-for-research-integrity

The invitation letter and the informed consent will contain information on the DPO of the WP3 leader (MEFST). All interviewees, regarding of the WP partner conducting the interview will be informed about DPO of the WP3 leader (MEFST).

4.7 Focus

We will conduct face-to-face and, if needed, online semi-structured interviews based on topic questions. In the case of online interviews, we will use the Skype Business platform which meets the requirements for the protection of personal data in alignment with the General Data Protection Regulation. In the case of conducting online interviews, we will use the visual and audio recording as this is provided by Skype.

Since the interviews will be conducted with experts, there is no need to explore their general knowledge about research integrity and research culture. The focus will be on more specific questions regarding the development and implementation of practices for RI in RPOs and RFOs, and managing violation of RI practices. Specific elements of a research culture that may have a positive or negative influence on the implementation will also be examined.

4.8 Contribution of WP partners

For the purposes of conducting a determined number of interviews, project partners involved in the WP3 will also be included. The ethics approval for conducting interviews will be requested from the University of Split School of Medicine for the overall study and, if needed, local ethics approvals will be sought by the partners performing interviews.

The split of the workload for performing 20 interviews is presented in the table below, taking into account the contribution to the work package and access to experts from different stakeholder groups. LSE will not be involved in this activity as it will be responsible for a part of Task 3.1 (Proposal for a multi-level model of research cultures and research conduct).

MEFST will conduct five initial interviews which will be analysed for identifying additional questions that may arise during the interview process. New questions and insights will be used to modify and complement the currently existing interview guide. A modified

interview guide will be disseminated to partners for the purpose of conducting interviews. MEFST and STICHTING VUMC will perform additional interviews if needed.

Table 3. The workload of WP partners in performing interviews

WP partner	*No. of interviews to be performed*	*Stakeholder target (tentative)*
STICHTING VUMC	4	RI committees, Industry
MEFST	8	Policy makers, Industry, RI committees
CWTS	2	Industry
KU Leuven	1	Researcher/educator
EARMA	2	Funding/process organisations
UNITN	2	RI committees
UNIWARSAW	1	Researcher/educator
Total	20	

Interview guide

The guide for conducting interviews is outlined below. If needed, it will be revised after the first five interviews.

Interview guide:

First, I would like to thank you for accepting our invitation to participate in this interview. As it was mentioned in the invitation letter, this interview will be conducted as a part of the Horizon 2020 project SOPs4RI (Standard Operating Procedures for Research Integrity).

The aim of the project is to create an online toolbox consisting of SOPs and guidelines for the promotion of research integrity in research performing organisations (RPOs) and research funding organisation (RFOs). These SOPs and guidelines will be offered as flexible tools for RPOs and RFOs to develop Research Integrity Promotion Plans.

To be able to create a toolbox containing best practices for RI, in this interview we would like to hear your experience with practices for the promotion of research integrity and their implementation within research organisations. Further, we would like to hear your opinion regarding the influence of research culture and thoughts about research misconduct.

I would like to point out that there are no right or wrong answers so please feel comfortable to express your opinion. Your opinion is very valuable to us and will contribute to the further development and the goal of the project.

This interview is confidential; hence everything said will be used, as mentioned in the invitation letter, only for the purposes of the SOPs4RI project.

During the interview, I will take notes and the conversation will be recorded. The recording is only to ensure we have all your answers. As we stated in the invitation letter the tapes will be stored for the period of five years after the last publication.

Do you agree for this interview to be tape-recorded?

This interview will last about an hour. If you don't have any additional questions we can start the interview.

1) Can you briefly tell us what behaviour you consider as responsible research conduct and what practices can help researchers to adhere to research integrity and responsible research conduct?

Possible probes:

- How can those practices be implemented into research institutions?
- How important is for the institution to develop and enforce rules which will be assembled as codes, guidelines and SOPs, and in which good and bad research practices will be described?

- In your opinion, should codes, guidelines, and SOPs be optional or mandatory for research institutions and whether researchers should be obligated to adhere to those norms?

2) What would you address as prominent reasons why researchers get involved in research misconduct?

Possible probes:

- Is research culture sufficiently detailed and what other practices, other than FFP, would you consider a violation of research integrity and which need to be regulated?
- How are factors such us publishing, obtaining funding for research, career perspectives, and the behaviour of supervisors influencing researchers to involve in research misconduct?

3) What would you address as the most important practices for avoiding research misconduct and what can be done by RPOs and RFOs to avoid research misconduct?

Possible probes:

- How important is the training of PhD-students and their mentors?
- In which way research integrity committees should deal with research misconduct?
- What do you think about rehabilitation exercises for researchers involved in research misconduct?
- How can funding agencies and journals contribute to the avoiding of research misconduct?

4) Which elements of research culture may have an impact on the implementation of RI practices (positive or negative) and what changes within research culture would be desirable?

Possible probes:

- Would publishing negative research results have any impact on the reducement of cases of research misconduct?
- What are the pros and cons of temporary and permanent job contracts in terms of conducting research and the researcher's career?

4.9 Ethical considerations

This study involves research with human subjects. Therefore, ethics approval will be obtained for conducting the study from the Ethics Committee of the University of Split School of Medicine. Additionally, ethical standards and guidelines of Horizon2020 will be rigorously applied. Participants will be provided with a description of the overall aim of the SOPs4RI project, the specific aim of the Delphi study, an outline of the procedures involved in the Delphi study, as well as the benefits and risks/burdens involved in participating. Informed consent will be obtained.

4.9.1 Participant burden and risk

As mentioned above, all information gathered through interviews will be used only for the purposes of SOPs4RI project and participants will have to give consent for recording the interview.

Despite that, participants may feel uncomfortable to discuss research misconduct and express opinion about possible negative factors influencing implementation of RI. They may risk discovering information about research misconduct within their institutions. In order to minimize this risk, i. e. to prevent mentioning of personal names and the possible stigmatisation of individuals, respondents will be asked not to provide personal information but rather present an anonymous case. If the case of serious scientific fraud or abuse is revealed during the interview, the Executive Board will be notified and the further decision about the specific case will be brought in consultation with the project consortium and legal experts.

The duration of the interviews will be about 1 hour. Before attending the interview, we will ask participants to complete a brief questionnaire (sent via email beforehand) about their background: gender, age, role regarding research integrity, years of experience, nationality and country of residence. The questionnaire will also include a couple of open questions about SOPs for research integrity. The template of the demographic questionnaire is presented in Appendix D.

4.9.2 Benefits of participation

Conducted interviews will provide the framework for the SOPs4RI project to build SOPs and guidelines for RI. This will help RPOs and RFOs to create plans with details to foster and promote responsible research practices, avoid detrimental practices and handle misconduct. Thus, participants will directly contribute to the development of better science and reduction of research waste. Moreover, exploring the relation of RI policies with other institutional policies, e.g. funding structures and career perspectives, can yield changes that will have an impact on the reduction of research misconduct cases (8).

4.9.3 Data management and privacy

We will ensure that our data management procedures comply with the General Data Protection Regulation (GDPR)[8] of the European Union. The procedures will be specified in the Data Management Plan (Deliverable D1.2).

4.10 Expected outputs

The expected outputs of this study include 1) this protocol, 2) interview analysis (deliverable D3.2) and 3) published article.

4.11 References

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5. Protocol for the Delphi procedure

5.1 Introduction

Although there is no single definition of research integrity (RI), it refers to conducting science responsibly and according to the highest professional, methodological and ethical standards (1). As such, RI is crucial for doing meaningful research. Unfortunately, recent findings show that RI is under threat by a high prevalence of both major (2%) and minor breaches (34%) of research integrity among scientists (2). This is thought to harm the validity of research findings and to contribute to the replication crisis that is affecting multiple scientific disciplines (3-5). In addition, problems with RI are thought to diminish society's trust in science, as well as the trust among researchers (6). In order to tackle these challenges, one of the most pressing concerns in research organizations in the European Research Area (ERA) is to foster RI among scientists.

Numerous codes of conduct have been published to foster RI, which provide scientists with aspirational values needed for conducting responsible research, including the European Code of Conduct on Research Integrity (ECoC) (7). Furthermore, different institutions have developed guidelines and standard operating procedures (SOPs) operationalizing these aspirational values into (detailed) procedures that scientists can perform in their everyday research practice. However, RI cannot be achieved by only providing codes, guidelines and SOPs to researchers. This is because the behaviour of individual researchers is dependent on the organisational culture that they work in. When organisations do not provide conditions that are conducive to RI, scientists are hindered in their ability to partake in responsible research practices (8). Furthermore, research funding has a significant influence on RI, as researchers' behaviours are also shaped by the way that funding is organised (9). Therefore, in order to effectively promote RI, research performing organisations (RPOs)[9] and research funding organisations (RFOs)[10] need to develop a culture that promotes RI. The EU Horizon 2020 project Standard Operating Procedures for

[9] For instance, research universities such as the Vrije Universiteit in Amsterdam

[10] For instance, national funders such as the National Institutes of Health in the USA

Research Integrity (SOPs4RI) aims to help RPOs and RFOs accomplish this by developing a toolbox of SOPs and guidelines, which organisations can use to develop their own research integrity promotion plans (RIPPs) in order to foster RI and avoid and handle research misconduct.

Since RPOs and RFOs are organisations which provide different support services to researchers (i.e. employment and facilities versus funding), we expect that they need different regulatory and procedural structures to foster RI. For instance, it is likely that RFOs influence researchers both directly (e.g. by providing requirements that must be completed by researchers to obtain funding) and indirectly (e.g. by requiring RPOs to have certain facilities available for researchers). Alternatively, RPOs mostly have a direct relationship with researchers; they can ask for a number of things from researchers to (continue to) give them access to facilities and employment (e.g. training and education requirements) Therefore, the two organisational types may need to be approached differently in the development of SOPs4RI's toolbox.

To build the toolbox, it is first necessary to identify what topics are important to include in it. Therefore, we will conduct a Delphi study to reach consensus among experts about which topics should be covered by the SOPs4RI toolbox for RI for a) RPOs and b) RFOs.

5.2 Aim

The main aim of the Delphi survey study is to obtain consensus from experts on topics that are important in relation to organisational efforts to foster RI and to avoid and handle research misconduct. More specifically, we will address the following research questions:

- What do experts consider to be the most important topics to consider, in the form of a taxonomy, for the creation of RPO RIPPs (and therefore which topics should be covered by SOPs4RI's toolbox)?
- What do experts consider to be the most important topics to consider, in the form of a taxonomy, for the creation of RFO RIPPs (and therefore which topics should be covered by SOPs4RI's toolbox)?

5.3 Methods

5.3.1 Preparation

In order to obtain consensus on a taxonomy of topics that should get attention in SOPs4RI's toolbox, based on a prioritisation of their importance, we will first create a preliminary list of topics to present to experts (presented in alphabetical order). Two separate lists will be made: one will be for topics relevant to RPOs and the other will be topics relevant to RFOs. The idea is that after the Delphi studies, the list will be edited and ordered based on expert consensus to produce one taxonomy of topics ranked in terms of importance for RPOs and another for RFOs. To produce the list of topics, we will do a non-systematic literature search of English language SOPs and guidelines on RI employed by organisations, written from 2000 onwards. To do the search, we will look at the website of one randomly selected RPO and one randomly selected RFO in each country in the ERA, as well as the USA, Canada and Australia. From the SOPs and guidelines identified, we will extract information on the type of document (i.e. SOP or guideline), scientific field and applicability to RPOs/RFOs. All members of the research group will be asked to scan the list and add additional topics they find relevant. Additionally, we will use data obtained from an ongoing systematic scoping review being performed by colleagues in SOPs4RI, on best practices of research integrity promotion in RPOs and RFOs, to update our list of topics when needed.

5.3.2 Contribution of WP partners

Table 4. The research group members for the Delphi consensus procedure

WP partner	*Contributors*
STICHTING VUMC	Krishma Labib, Joeri Tijdink, Lex Bouter, Guy Widdershoven, Wieneke Mokkink
MEFST	Rea Ščepanović, Ana Marušić

5.3.3 Participant recruitment

In a Delphi procedure, the panel members are carefully selected for their knowledge and interest in the field of research integrity policy. The panel members will be selected based on the following inclusion and exclusion criteria:

- *Inclusion criteria*
  - RI or research ethics policy experts who work in RPOs or RI or research ethics policy experts who work in RFOs;
  - The RPOs/RFOs that the panellists work in can be involved in research with different scientific backgrounds, since we would like to get a sample of panellists who work at RPOs/RFOs that represent diverse scientific backgrounds.
- *Exclusion criteria*
  - Experts in research integrity that do not work in RPOs and RFOs (e.g. those working in journals).

A minimum of 100 panellists will be invited to participate in the RPO study and RFO study each since we expect that 70% of the people invited will agree to participate (10, 11). Of those that agreed, we expect 65% will complete the first Delphi round, of which 75% will stay involved in the study (10, 11). Whether participants take part in the RPO or RFO study will depend on whether they have experience in RPO or RFO policy issues. We will identify suitable panel members by asking members of the SOPs4RI consortium to provide us with personal contacts that meet the inclusion criteria for participation, as well as by searching online for contacts for RI policies in 3 RPOs and 3 RFOs in each country in the ERA. We would like participants working in RPOs and RFOs with the following disciplinary focuses to be involved in the study: humanities, social sciences, natural sciences and biomedical sciences. If some scientific background is underrepresented, additional experts will be invited from that category. The identity of the panel members will be kept anonymous to the other panel members and to the research group (except for to KL who is responsible for corresponding with panellists).

5.3.4 Procedure

The Delphi procedure consists of a series of sequential questionnaires or 'rounds' containing proposals on different RI topics to include in SOPs4RI's toolbox, which a panel of experts can comment on. After each round's responses are analysed, they are fed back to the panellists as part of the next questionnaire with the aim of achieving a consensus of opinion among the experts (12). The Delphi procedure is a tool that can be used to generate debate and to structure, rank or organize a sample of topics (12). It is not a method for creating new knowledge, but a process for making the best use of available information and involving experts in the process of ordering information (12), although missing information will be explored by giving the panellists and researchers the option to make suggestions.

We will conduct two separate Delphi studies in parallel: one for topics for RPOs and one for RFOs. As can be seen in Figure 1, the rounds and procedures for each of the Delphi studies will be identical. In each round, we will ask panel members to rank topics from the list of topics in terms of importance. All panel members will be asked to give their opinion about each topic mentioned in the taxonomy and rate how strongly they (dis)agree to include the topic in the toolbox that SOPs4RI will be developing ("To what extent do you agree that the topic 'RI education' is important to consider when developing an organisational plan on fostering research integrity and avoiding and handling research misconduct (and therefore should be included in SOPs4RI's toolbox)?"). Ratings will be scored on a 10 point scale, with 1 indicating 'strongly disagree' and 10 indicating 'strongly agree'. Panellists will be asked to provide arguments for their ratings. They will also be given the opportunity to suggest alternative topics, to suggest additional elements within the topics, or to make any other comments on the list of topics.

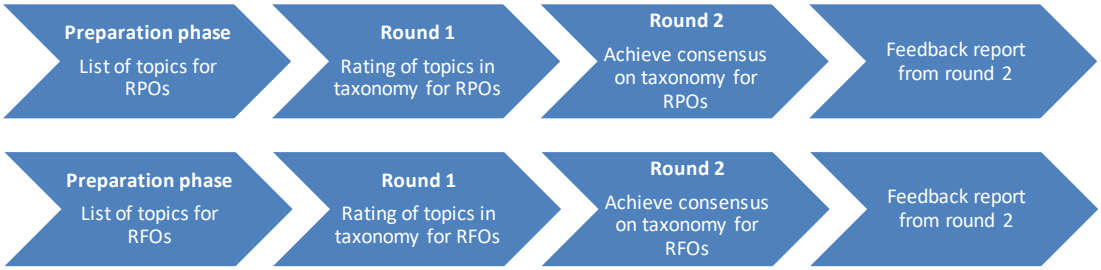

Figure 1. The Delphi procedure outlined. The procedures for the RPO study are shown on the top, whereas the procedures for the RFO study are shown on the bottom.

In the second questionnaires, a taxonomy based on the responses from the first surveys will be presented to panel participants. In this taxonomy, it will be indicated which topics panellists suggest to cover in the toolbox of SOPs and guidelines. Additionally, the scores and proposals for new topics from the first round will be provided in the second questionnaire. Based on the results of the ongoing scoping review on best practices of RI promotion in RPOs and RFOs, the researchers may also propose new topics to be included. The panel members will be asked again to give their opinion on each topic for which no consensus was reached in the first round, or for new topics proposed by the panellists or the research group. For these topics, panellists will be presented with arguments for and against the inclusion of the topic, as well as information on what per cent of respondents agreed to include the topic in the first round and what per cent disagreed. The topics for which consensus is reached will be selected for inclusion. Once the results of the second round have been analysed, a feedback report will be prepared and sent to all participants. Participants will be provided with the opportunity to respond to the report. Furthermore, they will be informed that we might contact them in the future for other SOPs4RI studies. They will be given the opportunity to opt out if they do not agree with this.

5.3.5 Data analysis

The results of each Delphi round will be presented both quantitatively (% scores 1-3 (disagree to include the topic); 4-6 (neutral) and 7-10 (agree to include the topic)) and qualitatively (the suggestions and comments of the panel members concerning each topic and arguments for or against the inclusion of this topic in the toolbox). Consensus will be considered to be reached when 67% of the panellists have a score of 7-10 on the scale.

5.4 Ethical considerations

This study involves research with human subjects. Therefore, ethics approval will be obtained for conducting the study from the VUmc Institutional Review Board and the VU Faculty of Behavioral and Movement Sciences Ethics Review Committee. Additionally, ethical standards and guidelines of Horizon2020 will be rigorously applied. Participants will be provided with a description of the overall aim of the SOPs4RI project, the specific aim of the Delphi study, an outline of the procedures involved in the Delphi study, as well as the benefits and risks/burdens involved in participating. Informed consent will be obtained.

There are no direct personal benefits of participation in this study. By participating, panellists will contribute to the development of effective SOPs and guidelines for RI, which will help RPOs and RFOs to foster RI and avoid and handle research misconduct. The study poses a small risk of discovering sensitive information, for instance about research misconduct cases or problems with how specific institutions deal with research integrity issues. We will take all steps necessary to minimise this risk by asking all participants to not provide names of people/institutions in the survey, and by (pseudo)anonymising all data before sending it to others. The burden for the panellists includes a maximum of 30 minutes they need to spend per Delphi round.

5.4.1 Data management and privacy

We will ensure that our data management procedures comply with the General Data Protection Regulation (GDPR)[11] of the European Union. The procedures will be specified in the Data Management Plan (Deliverable D1.2).

5.5 Expected outputs

The expected outputs of this study include this research protocol, the two surveys, two finished taxonomies based on experts' consensus (one for RPOs and one for RFOs), a report to the European Commission, as well as a final publication.

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Appendices

5.7 Appendix A. Search strategies for scoping reviews

5.7.1 Scopus

(TITLE-ABS-KEY(research W/3 (integrity OR ethics OR conduct OR misconduct OR malpractice OR manipulation OR fraud* OR honest*))) OR (TITLE-ABS-KEY((scientific OR academic) W/3 (fraud OR ethics OR integrity OR misconduct OR honesty OR dishonesty))) OR (TITLE-ABS-KEY((researcher* OR scientist*) W/3 (integrity OR honest*))) OR (TITLE-ABS-KEY((publication* or publishing) W/3 (ethics OR plagiari* OR falsif*)) OR (TITLE-ABS-KEY((author* OR contribut*) W/3 (undeserv* OR ghost OR guest OR gift*)))) AND ((TITLE-ABS-KEY(code W/3 (ethic* or conduct)) OR (TITLE-ABS-KEY(educat* OR teach* OR train* OR motivat* OR instruct* OR interven* OR promot* OR supervis* OR mentor*)) OR (TITLE-ABS-KEY(course* OR seminar* OR workshop*)) OR (TITLE-ABS-KEY((program* OR plan* OR policy OR rule* OR procedure* OR standard* OR code*) W/3 (formulat* OR develop* OR improve* OR expand*))) OR (TITLE-ABS-KEY(quality control))) AND (TITLE-ABS-KEY((ethics or research or grant or grants) W/3 (committee or committees or commission or commissions))) OR (TITLE-ABS-KEY(research W/3 (organisation* OR organization*)) OR (TITLE-ABS-KEY(universit$ or college or colleges)) OR (TITLE-ABS-KEY (universit* AND (faculty or faculties or school or schools or department or departments or laboratory or laboratories or lab or institut or institute or institutes))) OR (TITLE-ABS-KEY(academic or academia or higher education*))))

5.7.2 Web of Science

20 #19 AND #13 AND #6

19 #18 OR #17 OR #16 OR #15 OR #14

18 TS=(academic OR academia OR higher education*)

17 TS=(universit* AND (faculty OR faculties OR school OR schools OR department OR departments OR laboratory OR laboratories OR lab OR institut OR institute OR institutes))

16 TS=(universit* OR college OR colleges)

15 TS=(research NEAR/3 (organisation* OR organization*))

14 TS=((ethics OR research OR grant OR grants) NEAR/3 (committee OR committees OR commission OR commissions))

13 #12 OR #11 OR #10 OR #9 OR #8 OR #7

12 TS=(quality NEAR/3 control*)

11 TS=((program* OR plan* OR policy OR rule* OR procedure* OR standard* OR code*) NEAR/3 (formulat* OR develop* OR improve* OR expand*))

10 TS=(course* OR seminar* OR workshop*)

9 TS=(educat* OR teach* OR train* OR motivat* OR instruct* OR interven* OR promot* OR supervis* OR mentor*)

8 TS=(code NEAR/3 (ethic* or conduct))

7 TS=(guideline*)

6 #5 OR #4 OR #3 OR #2 OR #1

5 TS=((author* OR contribut*) NEAR/3 (undeserv* OR ghost OR guest OR gift*))

4 TS=((publication* OR publishing) NEAR/3 (ethics OR plagiari* OR falsif*))

3 TS=((researcher* OR scientist*) NEAR/3 (integrity OR honest*))

2 TS=((scientific OR academic) NEAR/3 (fraud OR ethics OR integrity OR misconduct OR honesty OR dishonesty))

1 TS=(research NEAR/3 (integrity OR ethics OR conduct OR misconduct OR malpractice OR manipulation OR fraud* OR honest*))

5.7.3 Medline

1 Scientific Misconduct/ (5023)

2 Fraud/ (7036)

3 exp Ethics, Research/ (7574)

4 (research adj3 (integrity or ethics or conduct or misconduct or malpractice or manipulation or misleading or mispresent$ or bias$ or fraud$ or honest$ or reliab?l$ or fair$ or impartial$ or selective$)).tw. (15995)

5 ((scientific or academic) adj3 (fraud or ethics or integrity or misconduct or malpractice or manipulation or honesty or dishonesty)).tw. (2418)

6 ((researcher$ or scientist$) adj3 (integrity or honest$)).tw. (92)

7 Plagiarism/ (1214)

8 (plagiari$ or falsif$).tw. (3121)

9 Publication Bias/ (4693)

10 Duplicate Publication as Topic/ (757)

11 Retraction of Publication as Topic/ (594)

12 Peer Review, Research/ (6325)

13 (data adj3 (interpretat$ or inaccura$ or inadequa$ or deceptive or deceit or bias$ or impartial or manipulat$ or misus$ or misleading or mispresent$ or mistreat$ or selective or suppress$ or fabricat$ or fraud$ or falsif$ or false)).tw. (27201)

14 Research Report/ (2769)

15 (report$ adj3 (selective or deceptive or deceit or misleading or inadequate or independent)).tw. (6958)

16 (research adj3 (underreport$ or under-report$)).tw. (43)

17 ((publication$ or publishing) adj3 ethics).tw. (485)

18 (bias adj3 (publication$ or publishing or analys#s or design)).tw. (13061)

19 (publication$ adj3 (rendundant or duplicate or multiple or salami or undeserving)).tw. (875)

20 (inaccura$ adj3 citation$).tw. (17)

21 Authorship/ (5535)

22 ((author$ or contribut$) adj3 (undeserv$ or ghost or guest or gift$)).tw. (258)

23 Conflict of Interest/ (9252)

24 (interest adj3 (conflict or competing)).tw. (4281)

25 or/1-24 (108903)

26 exp guideline/ (31503)

27 guideline$.tw. (304028)

28 exp "Codes of Ethics"/ (5164)

29 (code adj3 (ethic$ or conduct)).tw. (2457)

30 exp Education, Professional/ (282429)

31 exp Teaching/ (80510)

32 exp Curriculum/ (79237)

33 Mentors/ (9918)

34 (educat$ or teach$ or train$ or motivat$ or instruct$ or interven$ or promot$ or supervis$ or mentor$).tw. (2738959)

35 (course$ or seminar$ or workshop$).tw. (612665)

36 Policy/ (2054)

37 exp Policy Making/ (24148)

38 Program Development/ (27358)

39 ((program$ or plan$ or policy or rule$ or procedure$ or standard$ or code$) adj3 (formulat$ or develop$ or improve$ or expand$)).tw. (181855)

40 Quality Control/ (46654)

41 (quality adj3 control$).tw. (50594)

42 or/26-41 (3811000)

43 exp Ethics Committees/ (9027)

44 ((ethics or research or grant or grants) adj3 (committee or committees or commission or commissions)).tw. (13582)

45 (research adj3 organi#ation$).tw. (8560)

46 Universities/ (36926)

47 (universit$ or college or colleges).tw. (416213)

48 (universit$ and (faculty or faculties or school or schools or department or departments or laboratory or laboratories or lab or institut or institute or institutes)).tw. (106436)

49 (academic or academia or higher education$).tw. (129189)

50 or/43-49 (560208)

51 25 and 42 and 50 (6001)

5.7.4 PsychINFO

1 fraud/ (809)

2 professional ethics/ (18329)

3 (research adj3 (integrity or ethics or conduct or misconduct or malpractice or manipulation or misleading or mispresent$ or bias$ or fraud$ or honest$ or reliab?l$ or fair$ or impartial$ or selective$)).tw. (11366)

4 ((scientific or academic) adj3 (fraud or ethics or integrity or misconduct or malpractice or manipulation or honesty or dishonesty)).tw. (1345)

5 ((researcher$ or scientist$) adj3 (integrity or honest$)).tw. (77)

6 plagiarism/ (240)

7 (plagiari$ or falsif$).tw. (2533)

8 peer evaluation/ (2761)

9 peer review$.tw. (7868)

10 (data adj3 (interpretat$ or inaccura$ or inadequa$ or deceptive or deceit or bias$ or impartial or manipulat$ or misus$ or misleading or mispresent$ or mistreat$ or selective or suppress$ or fabricat$ or fraud$ or falsif$ or false)).tw. (7597)

11 (report$ adj3 (selective or deceptive or deceit or misleading or inadequate or independent)).tw. (1707)

12 (research adj3 (underreport$ or under-report$)).tw. (17)

13 ((publication$ or publishing) adj3 ethics).tw. (183)

14 (bias adj3 (publication$ or publishing or analys#s or design)).tw. (2638)

15 (publication$ adj3 (rendundant or duplicate or multiple or salami or undeserving)).tw. (150)

16 (inaccura$ adj3 citation$).tw. (13)

17 ((author$ or contribut$) adj3 (undeserv$ or ghost or guest or gift$)).tw. (452)

18 Conflict of Interest/ (564)

19 (interest adj3 (conflict or competing)).tw. (1343)

20 or/1-19 (54985)

21 guideline$.tw. (58798)

22 (code adj3 (ethic$ or conduct)).tw. (2909)

23 education/ (32620)

24 teaching/ (42029)

25 curriculum/ (25054)

26 mentor/ (5836)

27 (educat$ or teach$ or train$ or motivat$ or instruct$ or interven$ or promot$ or supervis$ or mentor$).tw. (1395167)

28 (course$ or seminar$ or workshop$).tw. (200665)

29 exp policy making/ (68897)

30 exp program development/ (8798)

31 ((program$ or plan$ or policy or rule$ or procedure$ or standard$ or code$) adj3 (formulat$ or develop$ or improve$ or expand$)).tw. (67869)

32 quality control/ (1434)

33 (quality adj3 control$).tw. (3335)

34 or/21-33 (1597178)

35 ((ethics or research or grant or grants) adj3 (committee or committees or commission or commissions)).tw. (2402)

36 (research adj3 organi#ation$).tw. (8713)

37 colleges/ (13109)

38 (universit$ or college or colleges).tw. (327580)

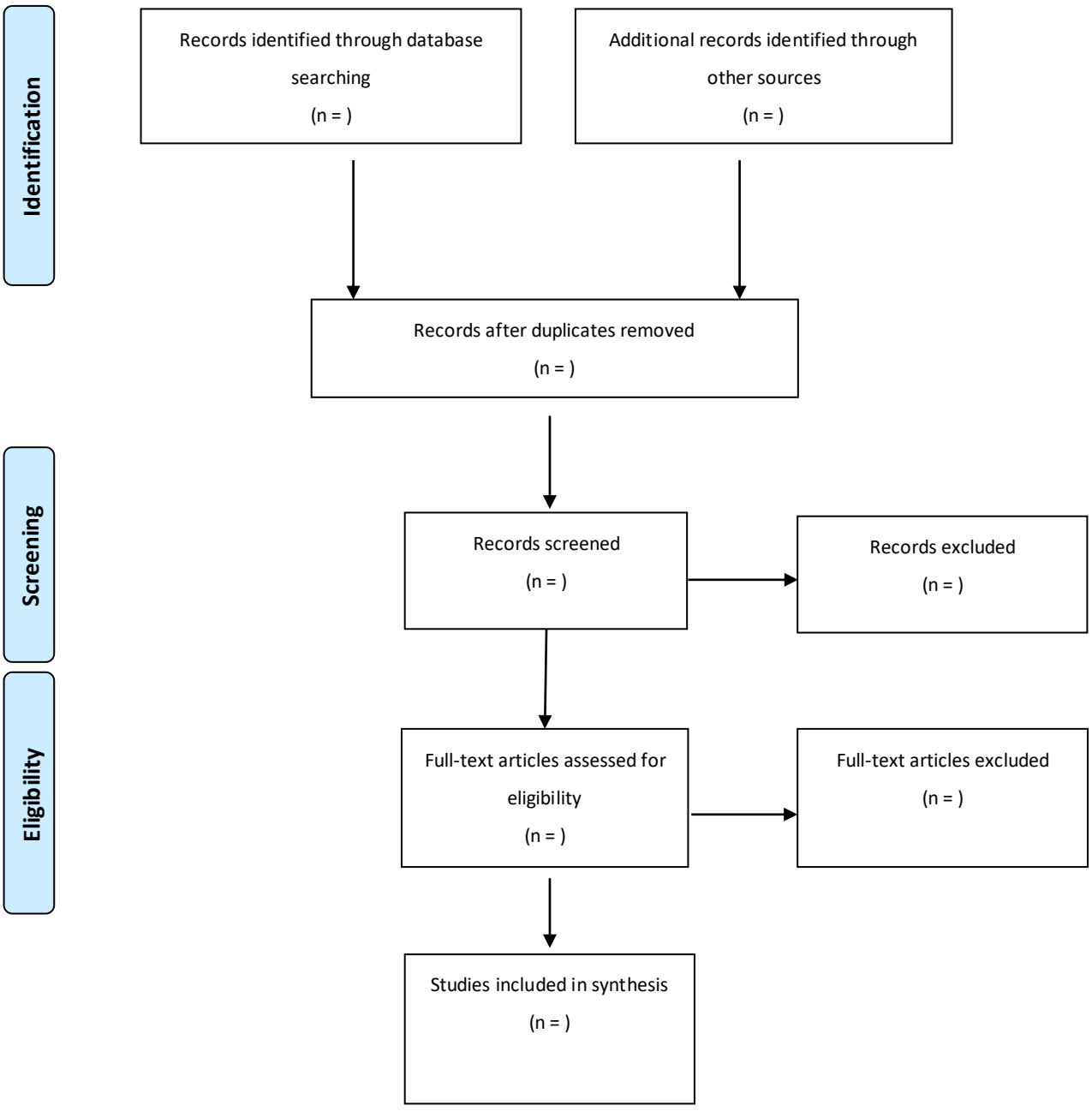
39 (universit$ and (faculty or faculties or school or schools or department or departments or laboratory or laboratories or lab or institut or institute or institutes)).tw. (45016)

40 (academic or academia or higher education$).tw. (156810)

41 or/35-40 (451152)

42 20 and 34 and 41 (5330)

5.8 Appendix B. PRISMA flow diagram for the scoping review process



5.9 Appendix C. Template of the information sheet and informed consent form for interviews

Note: This document will be revised according to the Data Management Plan (deliverable D1.2) and Ethical requirements (deliverables D8.1 and D8.2).

Information in red must be adapted based on the location of the interview(s).

Invitation to participate in the interview and informed consent for the stakeholder consultation 'Standard Operating Procedures for Research Integrity (SOPs4RI)'

Dear Sir/Madam,

The Horizon 2020 project SOPs4RI aims to contribute to the promotion of excellent research and a strong research integrity culture aligned with the principles and norms of the 'European Code of Conduct for Research Integrity' (ALLEA 2017). We at the SOPs4RI project aim to collect existing standard operating procedures and guidelines and to develop them further for the implementation in research performing organisations and research funding organisations across Europe. We will create an online toolbox taking into account differences between disciplines and countries. The toolbox will present key elements, i.e. standard operating procedures and guidelines, which will help research performing organisations and research funding organisations create their own institution-tailored Research Integrity Promotion Plans (RIPP).

We would like to invite you to participate in this stakeholder consultation via participation in the interview. By agreeing, you commit to participating in the face to face or online interview (depending on your schedule and availability). As this is a Europe-wide consultation, the language of the interview will be English. The interviews will be conducted anytime from March to June.

Hereafter you can read details about the project and the stakeholder consultation so you can make an informed decision whether you would like to participate in the interview or not.

1. The aim of the research

To create a toolbox of standard operating procedures and guidelines for Research Integrity Promotion Plans it is important to gain a better understanding of existing professional rules, practices, and factors influencing their implementation. The interviews with experts in the field of research integrity will provide us with additional knowledge on general elements for fostering research integrity in research performing organisations and research funding organisations. In this interview, we would like to hear your experience regarding practices for the promotion of research integrity and their implementation within research organisations. Further, we would like to hear your opinion regarding the influence of research culture and thoughts about research misconduct.

Knowledge gained through the interviews, together with previously conducted literature search, will be used as a basis for the further development of the project and the discussion for the Delphi survey and focus groups. Ultimately, the knowledge gained in this project will be used for the development of the toolbox, consisting of standard operating procedures and guidelines, which can be applied among different academic disciplines.

2. What do we ask from you?

If you would like to participate, the interview will be conducted by the researcher from the University of Split School of Medicine. The estimated duration of the interview is up to 1 hour. Before attending the interview, we will ask you to complete a brief questionnaire (sent via email beforehand) about your background: gender, age, role regarding research integrity, years of experience, nationality and country of residence. The questionnaire will also include a couple of open questions about SOPs for research integrity. You can bring the printed survey answers to the interview or fill them in before the interview. If you decide to participate in the online interview we kindly ask you to send us a filled survey via e-mail.

3. Benefits and risks of participating

Interviews with research integrity experts are essential for the development of the framework for the SOPs4RI project which will enable us to build a toolbox with SOPs and guidelines for the promotion of research integrity. This will help research performing organisations and research funding organisations to create plans with details to foster and promote responsible research practices, avoid detrimental practices and handle

misconduct. Thus, by sharing your knowledge and experience you will help us contribute to the development of better science.

The risk associated with the interview is that participants may feel uncomfortable to discuss research misconduct and express opinion about possible negative factors influencing implementation of research integrity practices.

To avoid possible risks we would like to point out that information provided during the interview are confidential. Moreover, if you would like to provide an example of research misconduct we advise you not to mention personal information or personal names but rather present an anonymous case. This way the cases presented in the interview will not be directly linked with the specific organisation or individuals.

Your personal data provided during the interview will be anonymised in the course of the transcription process. The information provided during the interview will not be linked with a specific participant. The information will be connected only with the type of stakeholder (researcher, member of the RI committee, funding and process organisations employee, policy-makers or industry employee).

The information provided during the interview will be used only for the purposes of the SOPs4RI project.

4. If you decide not to participate or to withdraw from the interview

Participation in the interview is voluntary. **If you decide to participate, we kindly ask you to sign the attached informed consent and return it to us via the e-mail.**

If you have agreed to participate but change your mind, you can withdraw at any point (including during the interview). When you withdraw from the study, all your non-anonymised data will be destroyed. If your data has already been analysed, the results will be used but the source of the data will not be retrievable.

5. Data processing and storage

Storage and use of the data collected during the interview will be in alignment with the data protection procedures contained in the European Union Law, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation - applicable as of 25 May

2018 in all European Union member states) and Danish Ministry of Higher Education and Science's recommendation in the Danish Code of Conduct for Research Integrity - Section II. 2. 1. i. (https://ufm.dk/en/publications/2014/the-danish-code-of-conduct-for-research-integrity). All data collected through the interviews will be stored on the SharePoint, a web-based collaborative platform, administered by the project coordinator, i.e. Aarhus University. The access to the stored data will be enabled only for the partners of the SOPs4RI consortium.

The ethics approval for conducting all interviews in the Work Package 3 has been obtained by the Ethics Committee at the University of Split School of Medicine.

If you decide to participate in the online interview, we would like to point out that the Skype Business platform is GDPR compliant.

All collected data will be stored for the period of five years after the last publication. This includes original audio-visual files, transcriptions, signed consent forms and questionnaires. Only anonymised data will be used for analysis.

In line with the open access movement, we will make the anonymised data publicly available on the Open Science Framework. If we notice that there is any data that even after anonymisation has the potential to be sensitive, we will send it to you to obtain consent to either deleting it, anonymising it further or making it publicly accessible. If you would like to have access to your non-anonymised data (stored encrypted on SharePoint), you can always contact Rea Scepanovic (rea.scepanovic@mefst.hr) to have it sent to you. 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: https://cordis.europa.eu/en.

6. Financial aspects

There is no fee paid for participation in the study.

7. Do you have any questions?

Please do not hesitate to contact, Prof. Ana Marušić, MD, PhD, ana.marusic@mefst.hr, if you have any questions.

If you would like to contact Data Protection Officer at the University of Split School of Medicine for additional information regarding data protection, privacy issues, and use of data in this research please use this address: dpo@mefst.hr.

Informed consent and confidentiality agreement

Please read the statements below in connection with the research 'Standard Operating Procedures for Research Integrity (SOPs4RI): stakeholder consultation – interviews'. By singing the consent you indicate you are in the agreement **with all** of the statements below.

- I have read the information provided about the study. I had the opportunity to ask questions and my questions have been sufficiently answered. I have had enough time to decide whether I would like to participate.
- I am aware that participation in the study is voluntary. I also know that I can decide at any moment to not participate or withdraw from the study. I do not have to provide any reasons for not participating or terminating enrolment in the study.
- I give consent to the audio recording of the interview (and video recording for online interview).
- I give consent to the collection and use of my data as described in the information sheet. I give consent to having my data stored for five years on SharePoint after the study has been completed.
- I give consent to having my anonymised data publicly available. I understand that this means that the anonymised data can be used for research purposes other than the ones described in the information sheet. I am also aware that this means that my anonymised information may be used in countries outside of Europe and that the regulations for data processing and storage in those countries may not comply with those of the European Union.
- I want to participate in this study.

Name:

Signature: Date: __ / __ / __

5.10 Appendix D. Template of the demographic questionnaire for interviews

As stated in the invitation letter, this questionnaire is a part of the SOPs4RI project task related to the expert interviews. The questions address your demographic data (gender, age, nationality and country of residence) and questions concerning information relevant for research integrity and standard operating procedures (SOPs).

Storage and use of the personal data collected through the questionnaire will be in alignment with the data protection procedures stated in the invitation letter.

Your age (in years): _____

Your gender: a) Male b) Female c) Prefer not to say

Country of residence: _____

1. How are you involved in research?

a) Researcher/educator

b) Member of research integrity committee

c) Funding and process organisations

d) Policymaker

e) Industry

2. Years of work experience related to research integrity: _____

3. Can you specify 3 characteristics of SOPs that are, in your opinion, crucial for their quality? (e.g. if SOPs should be clear, detailed, extensive, up to date, action-oriented etc.)

4. Can you give us an example of SOP containing characteristic you specified above and that is, in your opinion, an example of good SOP for research integrity?

5.11 Appendix E. Template of the information leaflet for Delphi survey

Information leaflet

The leaflet will be presented to participants at the beginning of the Delphi survey. There will be a link that participants can click on to read about the sections on the benefits and risks of participating, withdrawing from the study, and data processing and storage. The rest of the information will be presented directly on the first page of the survey.

Information in red must be adapted based on 1) whether the participants work in a research performing or research funding organisation and 2) which topics are included in the list of topics.

Topics for standard operating procedures and guidelines on research integrity

Dear Madam/Sir,

We at the SOPs4RI project aim to create a publicly available toolbox containing standard operating procedures (SOPs) and guidelines that research performing organisations (RPOs) and research funding organisations (RFOs) can use to create their own institutionally tailored research integrity promotion plans.

Before we can create this toolbox, we need your help in identifying the most important topics that should be included in it, based on the needs of RPOs/RFOS. We believe that your experience in research integrity policy will be valuable in seeing what are the most important topics for research integrity promotion in RPOs/RFOs. Therefore, we would like to invite you to participate in this Delphi study.

1. The aim of the research

The aim of the Delphi study is to identify important topics to include in our SOPs and guidelines on research integrity for research targeted at RPOs/RFOs, based on expert experience and opinion. The goal is to obtain consensus on a taxonomy of topics relevant for research integrity promotion in RPOs/RFOs, based on the priority of importance. Based on the outcome of the Delphi study, we will develop a toolbox of SOPs and guidelines on the topics indicated. These will provide tools and guidance to RPOs/RFOs on how to set up

institutional regulatory structures and procedures necessary for fostering research integrity.

2. What do we ask from you?

We ask you to fill in two surveys on research integrity topics. Each survey will take approximately 30 minutes to fill in. You will be asked to fill in some demographic information (gender, country of work, scientific discipline of RPO/RFO that you work in, and years of experience). Additionally, you will be asked to comment on a taxonomy of topics that we provide you with, based on a review of the literature, by rating topics on a 1-10 scale in terms of importance, providing arguments for your rating. You will also be encouraged to provide additional comments and suggest other relevant topics that we may have missed in the preliminary taxonomy.

After each Delphi round, the ratings, arguments and proposed additions will be summarised and sent to all participants. This will be done in order to provide you with an overview of others' responses and to give you the opportunity to comment on our analysis. Your personal information will be kept strictly confidential throughout this process; all data sent to the other participants and researchers (except for Krishma Labib, who is responsible for corresponding with you) will be anonymised. For more information on the benefits/risks of the study, withdrawing from the study and data management, please click on this link:....

If you have any questions about this information, please feel free to contact Krishma Labib (k.labib@vumc.nl).

Kind regards, on behalf of the whole research team from Amsterdam University Medical Centers, Location VUmc (Netherlands) and University of Split School of Medicine (Croatia),

Krishma Labib, MSc, MA

Dr Joeri Tijdink

Below is the material that can be found when clicking on the link:

3. Benefits and risks of participating

There are no direct personal benefits of participation in this study. By participation, you will contribute to the development of effective SOPs and guidelines for research integrity, which will help RPOs/RFOs, including your own institution, to foster research integrity and

avoid and handle research misconduct. The study poses a small risk of discovering sensitive information, for instance about research misconduct cases or problems with how specific institutions deal with research integrity issues. We will take all steps necessary to minimise this risk by asking all participants to not provide names of people/institutions in the survey, and by anonymising all data before sending it to others. The burden of participating includes 30 minutes of time completing each survey.

4. If you decide not to participate or to withdraw from the study

Participation in this study is voluntary. If you do not want to participate, you can close the browser or tab. If you would like to participate, please click on the 'Agree' button found at the bottom of this page. If you initially decide to participate but change your mind later, you are free to withdraw. We would appreciate it if you would send us an email informing us of this. However, you do not have to provide us with reasons for the termination of your participation. When you withdraw from the study, all your non-anonymised data will be destroyed. If your data has already been analysed, the results will be used but the source of the data will not be retrievable.

5. Data processing and storage

We will use the survey program Survalyzer to do online surveys. Once the two surveys are matched, they will be decoupled from email addresses. Additionally, only Krishma Labib will have access to your personal information during the conduct of the study, for the purposes of correspondence. All others, including other researchers and study participants, will only receive data once it has been (pseudo)anonymised (and if relevant, aggregated).

Storage and use of the data collected during the study will be in alignment with the data protection procedures contained in the European Union Law, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation - applicable as of 25 May 2018 in all European Union member states) and Danish Ministry of Higher Education and Science's recommendation in the Danish Code of Conduct for Research Integrity - Section II. 2. 1. i. (https://ufm.dk/en/publications/2014/the-danish-code-of-conduct-for-research-integrity). All data collected through the interviews will be stored on the SharePoint, a web-based collaborative platform, administered by the project coordinator, i.e. Aarhus

University. The access to the stored data will be enabled only for the partners of the SOPs4RI consortium.

The ethics approval for conducting interviews is obtained by the Institutional Review Board of the Amsterdam University Medical Centres, Location VUmc and the Ethics Committee of the VU University Faculty of Behavioural and Movement Sciences.

All collected data will be stored for the period of five years after the last publication.

In line with the open access movement, we will make the anonymised data publicly available on the Open Science Framework. If we notice that there is any data that even after anonymisation has the potential to be sensitive, we will send it to you to obtain consent to either deleting it, anonymising it further or making it publicly accessible. If you would like to have access to your non-anonymised data (stored encrypted on SharePoint), you can always contact Krishma Labib to have it sent to you.

If you have any complaints about your use of data in this study, regarding privacy issues, you can always file a complaint to the Amsterdam University Medical Center Data Protection Officer (privacy@vumc.nl). You can also directly file a complaint to the Dutch authorities using the following URL: https://autoriteitpersoonsgegevens.nl/.

6. Financial aspects

There is no fee paid for participation in the study.

5.12 Appendix F. Template of the informed consent form for the Delphi survey

Informed consent procedure

Topics for standard operating procedures and guidelines on research integrity

In order to indicate informed consent, participants will have to click on 'Agree' at the beginning of the survey. If they do not want to participate, they can exit the browser/close the page. Below is the information that will appear on the screen.

By clicking on 'Agree', I indicate that:

- I have read the information provided about the study. I had the opportunity to ask questions and my questions have been sufficiently answered. I have had enough time to decide whether I would like to participate.
- I am aware that participation in the study is voluntary. I also know that I can decide at any moment to not participate or withdraw from the study. I do not have to provide any reasons for not participating or terminating enrolment in the study.
- I give consent to the collection and use of my data as described in the information leaflet. I give consent to having my data stored for five years on SharePoint after the study has been completed.
- I give consent to having my anonymised data publicly available. I understand that this means that the anonymised data can be used for research purposes other than the ones described in the information leaflet. I am also aware that this means that my anonymised information may be used in countries outside of Europe and that the regulations for data processing and storage in those countries may not comply with those of the European Union.
- I want to participate in this study.

AARHUS UNIVERSITY

VUmc

SVEUČILIŠTE U SPLITU
MEDICINSKI FAKULTET

University of Essex

ÖSTERREICHISCHE AGENTUR FÜR WISSENSCHAFTLICHE INTEGRITÄT

Universiteit Leiden

Health Research Board

KATHOLIEKE UNIVERSITEIT LEUVEN

LSE The London School of Economics and Political Science

EARMA

UNIVERSITAS VARSOVIENSIS

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