SOPs4RI

D4.1: Protocol for the development of SOPs and guidelines

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0.3	21.08.2019	Third draft	Niels Mejlgaard, Mads Sørensen
1.0	26.08.2019	Final version 1.0	Joeri Tijdink

Table of Contents

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

CBA – Cost Benefit Analysis

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 enable RPOs and RFOs to create and implement Research Integrity Promotion Plans (RIPPs). SOPs4RI will thus stimulate European organisations involved in performing and funding research to foster responsible conduct of research by organizational measures and policies. SOPs4RI takes a mixed-methods, co-creative approach to the identification, 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 identification and development of SOPs and guidelines will take national, epistemic, and organisational differences into account, and the final toolbox will enable RFOs and RPOs to create Research Integrity Promotion Plans in accordance with the needs of their organisation.

1.4 About WP4 – Taking the necessary steps with a mixed method approach to streamline the process of identifying and developing SOPs and guidelines for RFOs and RPOs

Work Package 4 (WP4) serves as the backbone of the project. WP4 creates, improves, sharpens and finalizes the content of the toolbox with SOPs and guidelines designed to support RPOs and RFOs.

WP4 builds on WP3 and uses the inputs from the literature review, expert interviews and Delphi procedure to identify the themes to be tailored to different disciplines and the needs of RPOs and RFOs. The first draft of the toolbox with the SOPs and guidelines, version 1.0, will be used in the focus groups (WP5). With the feedback from the focus groups (researchers, experts, policy makers, private sector funding agency officers, etc.) WP4 creates the second version of the toolbox (version 2.0) with SOPs and guidelines. In the co-creation workshops with stakeholders this version is further improved to version 3.0.

Version 3.0 of the SOPs and guidelines will then be tested in the international survey (WP6) among researchers and other stakeholders. The survey will check the content of the toolbox and create further knowledge on national, organisational and disciplinary differences. The survey will include a cost-benefit analysis (CBA) to identify barriers for possible implementation of the toolbox. The implementation of version 4.0 of the toolbox will be piloted in a sample of RPOs and RFOs in WP7.

The final output of WP4 will be a ready-to-use toolbox with SOPs and guidelines for RPOs and RFOs (version 5.0).

The following components are part of WP4:

- Creating the first, second, third, fourth and fifth version of the SOPs and guidelines that we want to include in our toolbox.
- Conducting and reporting on the co-creation workshops
- Continuous communication and consultation with WP1 (coordination) and all the members of SOPs4RI to stick to the planning

1.5 About this deliverable

Deliverable 4.1 provides the detailed protocol for the identification and development process of the SOPs and guidelines (VUmc, M8). As such, deliverable 4.1 sets the scene for the other deliverables of WP4:

D.4.2. First version of SOPs and guidelines (VUmc, M13)
D.4.3 Second version of SOPs and guidelines (VUmc, M21)
D.4.4 Report on the co-creation workshops (KUL, M28)
D.4.5 Third version of SOPs and guidelines (VUmc, M26)
D.4.6 Fourth version of SOPs and guidelines (VUmc, M34)
D.4.7. Final toolbox with SOPs and guidelines (version 5.0) (VUmc, M48)

2. Detailed protocol for the development process of the SOPs and guidelines

2.1 Introduction

Work Package 4 creates the new versions of the SOPs and guidelines after every empirical step (review, Delphi, interviews, focus groups and survey). Furthermore, it creates content for the SOPs and guidelines by conducting the co-creation workshops and it is involved in the piloting and implementation phase of WP7.

In this process, WP4 will frequently seek advice from the Executive board and the Advisory Board to steer the process of forming and testing the SOPs and guidelines.

This part of the process bridges the empirical phases of the project and structures the content and form of the SOPs and guidelines that is are going to be created. The aim is to identify, draft, prepare, test, improve, and finalize the SOPs and guidelines that together will form the toolbox for Research Integrity Promotion Plans for RPOs and RFOs in the EU.

2.2 Work package objectives

The main aim:

To identify, draft, prepare, improve, test and finalize the SOPs and guidelines for the toolbox with input from the literature review, interviews, Delphi procedure (WP3), focus groups (WP5), survey (WP6) and pilot testing (WP7).

The following objectives are formulated to achieve this main aim:

1. To develop a toolbox with research integrity Standard Operating Procedures (SOPs) and guidelines for RPOs and RFOs, which reflect the principles and norms of the European Code of Conduct for Research Integrity (ALLEA 2017).

2. To streamline the process of all the steps in the projects (in close collaboration with WP1) within the 4 years of the project with the ultimate goal to deliver the toolbox.

3. To work with SOPs and guideline experts to construct specific SOPs and guidelines.

4. To ensure that the principles and norms of the European Code of Conduct for Research Integrity (ALLEA 2017) are translated into the drafts and final version of the toolbox.

5. To organise co-creation workshops with diverse stakeholders and incorporate their thoughts and ideas in the toolbox.

6. To help WP6 to validate and implement a procedure for a CBA (Cost Benefit Analysis) of the implementation of SOPs and guidelines.

7. To create the first, second, third, fourth and fifth version of the toolbox.

2.3 Methods

Task 4.1 Developing SOPs and guidelines version 1.0. (M 8-13, leader: VUmc, participants: HRB, All)

Introduction:

The knowledge output of WP3 (literature review, expert interviews, Delphi procedure) is translated into a first draft the of the toolbox with SOPs and guidelines (version 1.0). The consensus from the Delphi process provides the essential themes and elements that should be covered in the SOPs and guidelines. This first draft will be discussed and improved in the focus group interviews (WP5).

Specific activities: 1) Map the landscape of the most important issues that need to be covered in the toolbox, based on the knowledge acquired by WP3. 2) Identify and prepare SOPs and guidelines that can be discussed in the focus group interviews. 3) Flag important questions that need to be addressed in the focus groups. 4) Review round of discussion of the next draft (2.0) of the SOPs and guidelines with WP3 (back loop review to see if the content is interpreted correctly by WP4).

Aim:

The aim of task 4.1 is to map the 'landscape' of topics, subtopics and examples of SOPs and guidelines based on the results of WP3 (Delphi, Experts-Interviews, scoping reviews on best practices of research integrity promotion and on factors influencing the promotion of research integrity). This map will be created on the basis of the topics of the Delphi with additional topics that are formulated in the reviews and interviews. After creating this map of the landscape, we attach already existing SOPs and guidelines (examples), found in the empirical work, to the topics we want to create content for. Subsequently, we identify topics for which we need to develop new or modify existing SOPs or guidelines.

Procedure:

The first step in this process is the selection of topics to include in the toolbox, based on the results of the Delphi, the interviews and the systematic review. We combine the output from the reviews and the interviews with the 'consensuslist' of topics that is the result of the Delphi study. This selection is done on the basis of the consensus results and arguments from the Delphi and thorough discussion with the AB and Work Package leaders. We collect this knowledge from these empirical steps with the selected themes. Furthermore, we have to take into account that sometimes, the research group from WP4 needs to make decisions on what is realistic to include in our toolbox. Some topics and subtopics may need a new SOP or guideline, while others already have more integrated knowledge and need less efforts in creating the SOP/guideline.

In a second step, we use the knowledge gained from the scoping reviews on best practices of research integrity promotion and factors influencing the promotion of research integrity, together with the interviews with experts to supplement the topic list. On the basis of this knowledge, we will choose the topics and subtopics for which SOPs or guidelines are needed.. Here we will also draw on the advice of SOPs4RI's Advisory Board (AB). In the selection process, we use 3 key elements that guide our decision on selection. 1) we use our definition of RI to assess whether the topic falls within our definition, 2) we assess whether it is practically feasible (a content driven decision; ie is a SOP possible for research culture?) and 3) Is there a degree of salience for the practitioner/user of the SOP/guideline for this specific topic. These 3 steps will better guide our decision on whether or not a topic should be included in the toolbox and needs the creation of a SOP or guideline. Since we have limited time and resources, we cannot include all topics. The definition of RI can guide and inform us in the decision process. We will also identify existing examples of SOPs and guidelines that fall under the selected topics. The identified examples can be used in the development of the first drafts of the SOPs and guidelines and can be inspirational for WP5 (the focus groups).

The third step is to examine if there are multiple SOPs or guidelines for the same (sub)topics and to decide, which SOP or guideline are most suitable for the single topics.

The fourth step is to determine which (sub)topics so far have no examples of SOPs and guidelines available and where new SOPs or guidelines therefore need to be created. These topics should be flagged to the focus groups as topics that need special attention.

The fifth step is to create a preliminary sketch of the structure of the SOPs or guidelines per (sub)topic and use the content of the reviews, interviews and best practices to further shape and create the overall structure per topic. This will result in a rough picture of the SOP or guideline to be formed that will result in a SOPs or guidelines. Furthermore, we closely collaborate with WP5 to assure that we create a map of the landscape of topics for which SOPs and guidelines are needed – a map that can be used in the focus group study.

The sixth step is the finalizing of the first draft of the SOPs guidelines to make it usable for the focus group interviews (WP5). We do this by mapping out the (sub)topics that have gaps or limited resources. We make a first preliminary sketch of the toolbox and collaborate closely with WP5 to make the first draft useful and practical for the focus group interviews.

Task 4.2 Developing SOPs and guidelines version 2.0 (M 17-21, leader: VUmc, participants: KUL, EARMA, OeAWI, AU)

Introduction

The results of the focus groups will lead to new knowledge on where SOPs and guidelines are most needed and give us important information on disciplinary differences. This will help us identify in which areas (for which topics) we have to develop disciplinary differentiated SOPs and guidelines. This knowledge will be reviewed and will lead to a second version of the toolbox of SOPs and guidelines. In this phase, we also consult experts (from the Advisory Board and beyond) with experience in drafting SOPs and guidelines. They will comment on our drafts of the SOPs and guidelines and improve the quality, structure and content.

Specific activities:

1) transforming the information of the focus groups into version 2.0 of the SOPs and guidelines;

2) consulting SOPs and guideline experts;

3) raising specific issues that should be discussed in the co-creation workshops,

4) conducting a review round of discussion of the next versions of the SOPs and guidelines with WP5 (back loop review to see if the content is interpreted correctly).

The main aim of task 4.2 will be to collect and translate the information from WP5 (the focus groups) into a new understanding of which topics and subtopics need to be included in the toolbox. WP5 will create so-called 'heat maps' of the most important areas to pay attention to, according to the different disciplinary main fields (Humanities, Social sciences, Natural sciences and Medical science). This information will be used in the second draft of the toolbox, which will be used in the co-creation workshops. These so-called heat maps give insight into disciplinary field differences and highlight the most important topics per main field. With these heat maps, we will be able to identify the gaps of knowledge in the

first draft of the toolbox. With the heat maps, we can identify the content that needs to be included in the toolbox. The co-creation workshops will then be used to identify and create content for these areas. Thus, the heat maps will serve as the base for the co-creation workshops that deliver topic-specific content to the SOPs and guidelines.

Procedure

The first step consists of the collection of the focus group results, including the heat maps of topics and subtopics per disciplinary main field. We will use these results to improve the first draft of the SOPs and guidelines. These results will give us insights into the differences between disciplines and help us make the toolbox more useful for different research disciplines.

The second step examines which topics are more suitable for guidelines and which of them are more suitable for SOPs. This question is also addressed in the focus group interviews, and on basis of the feedback from the focus groups and with the help of experts, we will make a decision about which topics will be covered by SOPs and guidelines respectively.

The third step is to create a preliminary second version of the SOPs and guidelines and to send them to 20-30 experts, who will comment on the content.

The fourth step is to collect the feedback of the experts and make suggested changes to the drafts of the SOPs and guidelines.

The fifth step is to select (in close collaboration with the Advisory Board of SOPs4RI) the topics that we want to discuss and develop SOPs and guidelines for in the co-creation workshops.

The sixth step is to make the second draft of the SOPs and guidelines ready for the co-creation workshops. We will draft a list of content-items for all topics for which we would like to receive input. Make sure that all principles and norms from the European Code of Conduct (ALLEA 2017) are respected in this version of the toolbox.

Task 4.3 Co-creation workshops, developing SOPs and guidelines version 3.0 (M 12-28, Leader: KUL, participants: VUmc, EARMA, UoW)

Introduction:

The goals of the Co-creation workshops are to identify the main lacunae and controversial points in version 2.0. of the toolbox – and to create a new improved version of the toolbox. See above in task 4.2 what preparatory steps we will take to prepare the draft of the toolbox and select topics for the co-creation workshops. The topic list will be discussed in the co-creation workshops. In these workshops, the main aim is to collect the

content for the SOPs and guidelines for these topics. Furthermore, we will discuss other potential issues with the participants that should be included in the toolbox such as the potential effectiveness of SOPs and guidelines when they are ready to be used in practice. Finally, the co-creation workshops will also discuss models for monitoring the implementation of RIPPs.

Specific activities:

1) identification of participating stakeholders; we will take feasibility, budget and availability into account when we plan the workshops.
2) developing the protocol that will be used as guidance in the workshops
3) organizing and performing the co-creation workshops;
4) drafting the next version of the SOPs and guidelines (version 3.0);
5) flagging specific issues for implementation that can be tested in the survey and account for organisational, interdisciplinary differences and major differences between countries (WP6);
6) conducting a review round of discussion of the next versions of the SOPs and guidelines with the co-creation organisers (back loop review to see if the content is interpreted correctly).

Aim:

The main **aim** of task 4.3 is to use the co-creation workshops with experts in the field as the opportunity to collect content for the SOPs and guidelines. We will invite experts to four different workshops. In these workshops, we will create and discuss content related issues that should be addressed in the SOPs or guidelines per topic. A secondary goal will be the discussion of the implementation of the toolbox. As we already have accounted for disciplinary differences in the focus groups (WP5), we can here take institutional differences across countries into account. Since we are aiming to create a toolbox that works in all EU-countries, we need more country-specific knowledge on future implementation problems.

Procedure:

The **first step** is to write a detailed research protocol for the co-creation workshops. This protocol will elaborate more on the design we discuss in this document.

The **second** step is to identify the experts that we will invite. We will use existing databases of experts that are available (ENERI, EnRIO, VIRT^{2}UE, EARMA). Furthermore, we will identify geographical areas (Scandinavia and Northern Europe, Central Europe, Mediterranean

Europe and Eastern Europe) to get input from different countries and to provide information for different countries.

The third step is to plan and schedule the meetings (well ahead of time as agendas of experts fill fast). We will divide the workshops into 4 with different stakeholders. Workshop 1 and 2 are is composed with a heterogeneous sample of researchers and policy makers from different institutions and different countries. Workshop 3 and 4 are composed with a random set of policy makers from different institutions and different countries and depend on the content that is needed. We plan to have 2 different timeframes to conduct the first two and the last two workshops in order to use the information from the first 2 workshops to explore the gaps that are still missing in the toolbox and need extra input and content.

The fourth step is to identify the major gaps of knowledge in version 3.0 of the toolbox per topic, per discipline and per country, and create a list of content related issues that should be addressed in the workshops. The co-creation workshops are the first step in exploring major differences between countries and institutions. It will help us carving and crafting the content and raise specific issues related to institutional differences and country differences, that we can address in the survey (WP6). One of the primary goals of WP6 is to account for differences between countries and institutions.

The fifth step is to help our partners (LSE, UK) in translating the cost-benefit model they have developed into the survey (in cooperation with the LSE, George Gaskell and WP6). This issue will be discussed in the co-creation workshops.

The sixth step is to conduct the two first workshops. In them, we will identify with the experts useful knowledge that we can collect in the survey (WP6) and discuss with them, how we can use that information for further improvement of the toolbox. The workshops require some preparation and active involvement of all the participants that we are going to invite. This is step-by step process. The first phase is the preparation phase with setting goals. Formulating goals are important in methods that generate content. Successful application rests on carefully selecting the main directions of the created content. The second phase is the sensitization phase. Sensitizing is a process where participants are triggered, encouraged and motivated to think, reflect, wonder and explore in their own time and environment. We will send out little activities and exercises before the actual workshops. In the workshops, participants do content generating exercises. Participants receive instructions and sets of expressive components to express their thoughts and ideas. This is a continuous reflective step with dialogues, presentations and inspirational exercises.

The seventh step is communication and feedback. Conventional written reports sometimes fall short in communicating effectively. Interactive techniques may be used to enhance the

production of content and create new input for the design team to further improve the knowledge learned. After this step we will plan workshops 3 and 4. These workshops serve as the content-driven step of the process and help us to fill the gaps of knowledge.

The eighth step is to incorporate the rich and diverse findings of the workshops to create the next version of the toolbox with SOPs and guidelines and discuss with WP6 (survey) how to deliver and present the results in order to make sure that the results can be easily implemented and used in WP6 (the survey). Re-check if all principles and norms from the European Code of Conduct (ALLEA 2017) are represented in this version of the toolbox.

Task 4.4 Developing SOPs and guidelines version 4.0 (M 28-38, leader: VUmc, participants: KUL, EARMA, OeAWI, UoEx)

Introduction:

At this stage of the development process of the toolbox, we will review the results from the survey. The survey conducted by WP6 will provide insight into the value and impact of the topics, subtopics and relevant issues within the topics per SOP or guideline (in order of importance), as well as a list of items per topic that the participants do not consider relevant and important to be part of the final version of the toolbox and which thus can be excluded. Furthermore, the survey will help us identify similarities and differences across countries, organizations and disciplinary fields. It further provides information on possible problems for the implementation and applicability. This information is necessary to create a version of the toolbox that can be used in the pilot testing. With the help of experts (e.g. from the Advisory Board) a new version of the toolbox will be created (version 4.0).

Specific activities:

1) merging the information of the survey report into the new draft of the SOPs and guidelines (version 4.0);

2) consulting SOPs and guideline experts from the SOPs4RI Advisory Board;

3) adapting the SOPs and guidelines with special attention to possible implementation issues and practical information for successful implementation in institutions;

4) conducting a review round of discussion of the next versions of the SOPs and guidelines with WP6 (back loop review to see if the content is interpreted correctly).

Aim:

The aim of task 4.4 is to use the results of the survey and translate them into version 4.0 of the SOPs and guidelines that will be used to make the preliminary toolbox ready for the pilot testing in the next phase of the project (WP7).

In this phase, we use the AB, but also other experts from different countries to give comments on our plan on how to overcome differences between countries.

Procedure:

The first step is to discuss the survey results from WP6 with all partners and the Advisory Board. Then we use the data and knowledge of WP6 to further improve the SOPs and guidelines and make a plan on how to account for differences between countries and institutions.

The second step is to create the new draft of the toolbox with all the topics covered. In this draft, we have taken disciplinary field differences and country differences into account. Furthermore, the survey will also provide information on how to implement the toolbox in different countries and different institutions. This is helpful to write a responsible and effective implementation plan with WP7. Important in this step is to make sure that the WP7 lead will be involved.

The third step is to consult with experts about version 4.0 of the toolbox with SOPs and guidelines and help WP7 to formulate a preliminary implementation plan.

The fourth step is to discuss with WP7 how to align the implementation strategy with the last version of the toolbox. It is essential that the toolbox contains all the information necessary to make the implementation as easy as possible, also for the pilot institutions. This will help us maximize the potential of the toolbox and the implementation strategy.

The fifth step consists of creating the version 4.0 of the toolbox with SOPs and guidelines in which the implementation strategy is incorporated. This will contain all the information that can be used in the next phase of the project (the pilot testing).

Task 4.5 Developing the final version of the toolbox with SOPs and guidelines, version 5.0 (M 38-48, leader: VUmc, participants: KUL, OeAWI, HRB, All)

We will use the comments that are collected in the pilot testing phase by WP7 to create a final version of the toolbox with SOPs and guidelines.

Specific activities:

1) using the information of the pilot testing for the final version of the SOPs and guidelines and address all issues raised in the pilot testing report;

2) consulting SOP and guideline experts;

3) re-check if all principles and norms from the European Code of Conduct (ALLEA 2017) are represented in the final version of the toolbox;

4) Review round of discussion of the final versions of the SOPs and guidelines with WP7 (back loop review to see if content is interpreted correctly).

Aim:

The aim of task 4.5 is to finalize the toolbox (version 5.0) with SOPs and guidelines, have a second version of the implementation plan ready and make the toolbox online available (open access; in collaboration with WP2) for all institutions in Europe.

Procedure:

The first step is to use the information of the pilot testing to improve the toolbox with SOPs and guidelines. We will also help WP2 and WP7 to make an implementation plan that can be used in RPOs and RFOs.

The second step will be a final round of consultation with experts from our project, Advisory Board and other experts involved. We ask for final feedback on the toolbox. For this purpose, we will give a detailed description of the toolbox and the implementation plan and ask for feedback, specifically related to similarities and differences between disciplines and countries.

In the third step, we will check whether we managed to incorporate all the values and norms from the European Code of Conduct.

In the fourth step, we will review the toolbox for the last time and have a final round of discussion of the final version with all consortium partners in a concluding meeting.

The fifth step will include the uploading of the final version on the SOPs4RI website (and the website of the Embassy of Good Science) together with an implementation plan tailored per discipline and country and ready to be used by RPOs and RFOs. All members of our consortium will be actively involved in designing a specific strategy on how to implement the toolbox.

WP2 is closely collaborating with us during this phase of the project, as they design the online part of the toolbox. Therefore they need to be updated regularly to tailor their online web tool with the right information.

2.4 Planning:

Task 4.1: Developing SOPs and guidelines version 1.0

1 august 2019 – 31 January 2020

Task 4.2 Developing SOPs and guidelines version 2.0

1 May 2020 – 30 September 2020

Task 4.3 Co-creation workshops

1 December 2019 – 30 April 2021

Task 4.4. Developing SOPs and guidelines version 4.0

1 April 2021 – 28 February 2022

Task 4.5 Developing the final version of the SOPs and guidelines 5.0

1 February 2022 – 31 December 2022

Deliverables:

Deliverable	Date to send out for review	Deadline for submission
D.4.1. Detailed protocol for the development process of the SOPs and guidelines	31 July 2019	31 August 2019
D.4.2. First version of SOPs and guidelines (VUmc, M13)	31 December 2019	31 January 2020
D.4.3 Second version of SOPs and guidelines (VUmc, M21)	31 August 2020	30 September 2020
D.4.4 Report on the co-creation workshops (KUL, M28)	31 March 2021	30 April 2021
D.4.5 Third version of SOPs and guidelines (VUmc, M26)	31 January	28 February 2021
D.4.6 Fourth version of SOPs and guidelines (VUmc, M34)	30 September 2021	31 October 2021
D.4.7. Final toolbox with SOPs and guidelines (version 5.0) (VUmc, M48)	30 November 2022	31 December 2022

List of deliverables + important submission dates.

2.5 Contribution of WP partners

The work in WP4 described above will be led by Amsterdam UMC, location VUmc (Stichting VUMC). The work will be conducted in close collaboration with the other partners in WP4 and involve the leaders from the other WPs, as well as the coordinators from Aarhus University. The research group members are listed in the table below.

Table 1. The research group members for WP4: Development and implementation of the toolbox

WP partner	*Contributors*
STICHTING VUMC	Joeri Tijdink, Lex Bouter, Krishma Labib, Guy Widdershoven
MEFST	Ana Marušić (WP3)
AU	Niels Mejlgaard (WP1), Mads P. Sørensen (WP5)
KUL	Kris Dierickx, Daniel Pizzolato
OeAWI	Nicole Föger
University of Essex	Nick Allum
University of Leiden, CWTS	Wolfgang Kalltenbrunner, Andrea Reyes
NTUA	Costas Charitidis, Panagiotis Kavouras
HRB	Maura Hiney
LSE	George Gaskell
EARMA	Nik Claesen
University of Trento	Guiseppe Veltri
University of Warsaw	Anna Domaradzka

2.6 Expected outputs, apart from the deliverables.

The expected outputs of this study include:

1) The research protocol for WP4
2) The protocol of the co-creation workshops
3) Approval of the (medical) ethical review board
4) Privacy policy for the co-creation workshops
5) Report of the co-creation workshops

6) All the drafts of the toolbox with SOPs and guidelines
7) Final toolbox with SOPs and guidelines, available online

Appendix A list of preliminary topics for RI from the 1st round of the Delphi study (for RPOs and RFOs separately)

For RPOs: see here: https://osf.io/jc6u2/

For RFOs: see here: https://osf.io/82dwk/

Appendix B: list of members from the Advisory Board:

Representative	Organisation	Expertise relevant to SOPs4RI
1. Prof. James M. DuBois	Division of General Medical Sciences, John T. Milliken Department of Medicine, Washington University School of Medicine	Professor in Medical Ethics and Professionalism. Director of the Center for Clinical Research Ethics. Leads the Professional and Social Issues Lab, which has a special focus on helping researchers to conduct high-quality research with integrity by fostering good decision-making, management, and leadership practices.
2. Anja Gilis, PhD Director	Janssen Research & Development, a division of Janssen Pharmaceutica NV	Anja Gilis' areas of expertise covers quality management systems to ensure internal and external best practices for non-regulated research in a Pharma environment. She also works within the context of IMI project EQIPD (www.eqipd.org) as work package co-lead on the development of a flexible and fit for purpose quality management system for non-regulated research..
3. Zoë H. Hammatt, JD, MPhil	Z Consulting, LLC, USA	Licensed lawyer with a background in law and ethics in medicine. Ms. Hammatt has served on research misconduct investigation panels, ethics committees, as a Research Integrity Officer, and as Legal and Regulatory Specialist for a translational research network funded by the National Institutes of Health. In addition, she has had a leadership role at the U.S. Office of Research Integrity as its Director of the Division of Education and Integrity. She has developed SOPs for implementation at both the institutional and network level, and has experience in a federal agency charged with overseeing regulatory compliance for more than 4,000 research performing organisations around the world.
4. Prof. Judit Sandor	Central European University	Professor at the Central European University in Budapest and director of the Center for Ethics and Law in Biomedicine. Judit Sandor previously served as head of the bioethics Unit within UNESCO. Her expertise especially covers ethical and legal implications of new technologies and research. She has published 11 books in the field of human rights and bioethics.
5. Tony Mayer	Nanyang Technological University Singapore	Tony Mayer has been Research Integrity Officer at the Nanyang Technological University for the past decade and has extensive expertise within the area of research integrity. In his function as research integrity officer, he developed the university's research integrity policy and procedures and introduced training and education programs to promote research integrity and good research practice. Tony Mayer has been involved in policy developments at the national level in Singapore, at the European level, initially through the European Science Foundation and at the global level as the Co-Chair and co-organiser of the First, Second and Fifth World Conferences on Research Integrity.
6. Prof. Philippe Ravaud	Center of Research in Epidemiology and Statistics, Sorbonne Paris Cité	The expertise of Prof. Philippe Ravaud covers the development and implementation of reporting guidelines, interventional research on research with the aim of improving integrity, decrease waste in research and meta-research about detrimental research practices. Prof. Ravaud is member of the steering group of the Enhancing and Transparency of Research (EQUATOR) network.
7. Katie Metzler, Head of Methods Innovation	SAGE Publishing	As Head of Methods Innovation at SAGE Publishing, a leading independent academic publisher, the expertise of Katie Metzler especially covers aspects of research integrity related to the publication of the outputs of research. Katie Metzler has been working in publishing for over a decade, and in that time she has acted as commissioning editor for the world's leading research methods book list at SAGE, which has given her a uniquely broad overview of research practices across disciplines in the social sciences. In her role as Advisory Board member, she will pull together expertise across SAGE to represent the view of academic book and journal publishers, who occupy a central position in the academic research ecosystem.

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Health Research Board

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