

SOPs4RI

D7.1: Detailed protocol on how the pilot tests will be carried out and how the results will be analysed

Authors: Teodora Konach, Nicole Foeger, George Gaskell

Editors: Teodora Konach, Nicole Foeger

Project title: Standard Operating Procedures for Research Integrity Project acronym: SOPs4RI Grant Agreement no.: 824481 Lead contractor for this deliverable: Austrian Agency for Research Integrity



The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824481.





Coordination and Support Action H2020-SwafS-03-2018

Project full title

"Standard Operating Procedures for Research Integrity"

Project acronym

SOPs4RI

Grant Agreement no.

824481

D7.1: Detailed protocol on how the pilot tests will be carried out and how the results will be analysed

Editor:	Teodora Konach, Nicole Foeger
Version:	1.0
Dissemination Level ¹ :	PU
Author(s):	Teodora Konach, Nicole Foeger, George Gaskell

¹This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824481

PU – Public; PP - Restricted to other programme participants (including the Commission Services); RE - Restricted to a group specified by the consortium (including the Commission Services); CO - Confidential, only for members of the consortium (including the Commission Services).





Due date of deliverable:	30 April 2021
Actual submission date:	28 April 2021
Start date of project:	01 January 2019
Duration:	48 months
Organisation name of lead contractor for this deliverable:	OeAWI





Document metadata

Version	Date	Modification reason	Modified by
0.1	15.03.2021	First draft	Teodora Konach, OeAWI
0.2	30.03.2021	Second draft, modified following input from EARMA, AU, LSE	Teodora Konach, Nicole Foeger, OeAWI
0.3	06.04.2021	Third draft	Teodora Konach, Nicole Foeger, OeAWI; George Gaskell, LSE
0.3	08.04.2021	Review of deliverable	Serge Pascal Johannes M Horbach, AU
0.4	18.04.2021	Fourth draft	Teodora Konach, Nicole Foeger, OeAWI; George Gaskell, LSE
0.4	21.04.2021	Review of deliverable	Mads P. Sørensen, Serge Pascal Johannes M Horbach, AU
1.0	26.04.2021	Version for submission	Teodora Konach, Nicole Foeger, OeAWI; George Gaskell, LSE





Table of contents

1	INTE	RODUCTION	5
	1.1	ABBREVIATIONS	5
	1.2	TERMINOLOGY	5
	1.3	ABOUT SOPs4RI	6
	1.4	ABOUT THIS DELIVERABLE	7
2	PILC	DT TESTING	8
	2.1	INTRODUCTION	8
	2.2	METHODOLOGY	8
	2.2.1	THEORETICAL FRAMEWORK FOR THE PILOT TESTING	9
	2.2.2	SOP: POTENTIAL COSTS AND BENEFITS	. 10
3	IMP	LEMENTATION OF THE OBJECTIVES OF WORK PACKAGE 7	13
	3.1	SPECIFIC OBJECTIVES	15
	3.1.1 KUL	PILOT TEST OF THE TOOLBOX (M 24-44, LEADER: OEAWI, PARTICIPANTS: EARM , CWTS, NTUA, MEFST, AU, VUMC)	
	3.1.2 UoW	Conduct a cost-benefit analysis (M24-44, leader: LSE, participants: UC, CWTS, OEAWI, EARMA)	
4	EXP	ECTED SCIENTIFIC AND SOCIAL BENEFIT OF THE RESEARCH	22
5	EXP	ECTED OUTPUTS	23
6	DAT	A MANAGEMENT AND PRIVACY	24
7	CON	ITRIBUTION OF WORK PACKAGE PARTNERS	25
8	REF	ERENCES	27
A		ENDIX	~~





1 Introduction

1.1 Abbreviations

- CBA Cost Benefit Analysis
- ECoC European Code of Conduct
- FFP Falsification, Fabrication and Plagiarism
- QRP Questionable Research Practices
- RFO Research funding organisation
- RI Research Integrity
- RIPP Research Integrity Promotion Plan
- RPO Research performing organisation
- SOP Standard operating procedure

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 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-making 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

<u>SOPs4RI</u> (Standard Operating Procedures for Research Integrity) is a four-year (2019-2022), multi-partner transdisciplinary project funded by the European Commission (H2020-SwafS-03-2018, Grant Agreement no. 824481). The project has 13 partners in 10 European countries, and is coordinated by Aarhus University (AU). SOPs4RI has also been preregistered at the Open Science Framework: <u>https://osf.io/49fbk/</u>.

Objectives

The Standard Operating Procedures for Research Integrity (SOPs4RI) project aims to foster the promotion of excellent research and to strengthen research integrity culture, using the principles and norms of the European Code of Conduct for Research Integrity (ECoC) as a framework. The overall objective is to create an online, freely accessible toolbox to support and guide research performing organisations (RPOs) and research funding organisations (RFOs) in cultivating research integrity and consequently preventing, detecting and handling research misconduct.

In order to address the needs of both RPOs and RFOs, SOPs4RI takes a mixed-methods, co-creative approach to the development and empirical validation of SOPs and Guidelines. The pilot phase, as a final stage of refinement and validation, will test the SOPs and Guidelines in selected RPOs and RFOs.





1.4 About this deliverable

Deliverable 7.1. is the protocol on how the pilot tests will be carried out in the SOPs4RIproject. The pilot tests are described in detail as follows: first, the overall goal of the pilot test phase is introduced and the methodological framework for both pilot testing and cost-benefit analysis is discussed. Hereafter, the protocol describes the work package objectives. In this part each specific objective is presented and analysed, by explaining, in detail, steps that are planned. In the Appendix section the Preliminary Roadmap for Work Package 7 can be found.





2 Pilot testing

2.1 Introduction

The aim of WP7 is to test the SOPs and guidelines developed in SOPs4RI, and to empirically inform them in selected institutions that are representative of key players and stakeholders within the research community: public RFOs (Austrian Science Fund {FWF} and the Research Council of Norway {RCN}), private RFOs (La Caixa Foundation and Novo Nordisk Foundation) and four RPOs: Ghent University, Jagiellonian University, University Pompeu Fabra and Janssen Pharmaceutica N.V. (member of the European Quality in Preclinical Data project {EQIPD}). Taking a co-creating and participatory approach, the pilot tests will gather valuable and crucial input on practical issues related to implementing the SOPs and guidelines, by engaging with different stakeholders within each pilot institution. To achieve the work package objectives, SOPs4RI partners will be involved in different working groups (Task forces), working simultaneously on specific tasks, namely: (i) drafting an implementation guideline that will comprise a framework and concrete advice to both RPOs and RFOs on how to establish a RIPP and how to implement specific tools from the toolbox; (ii) introducing the main topics identified by the consortium to RFOs and RPOs (six and nine topics respectively) through general sessions with follow-up meetings for each pilot institution (Content Tours and Content Helpdesk), co-creating a RIPP, tailored to each institution's needs; and (iii) conducting the cost-benefit analysis.

Feedback from the pilot tests will be used to further improve and fine-tune the SOPs and guideline-toolbox, addressing the tools' effectiveness and efficiency, and providing valuable information 'in vivo' on the costs and benefits of these instruments.

The main outputs of the pilot tests are two reports: "Report on the Pilot Studies" (Deliverable 7.2.) and "Cost-Benefit Analysis" (Deliverable 7.3.). Both reports will be used in the development of the final version of the SOPs, guidelines and toolbox.

2.2 Methodology

The development of the SOPs and guidelines within the SOPs4RI-project is grounded in a mixed-methods and co-creational approach through all four cycles of research within the project (Figure 1).

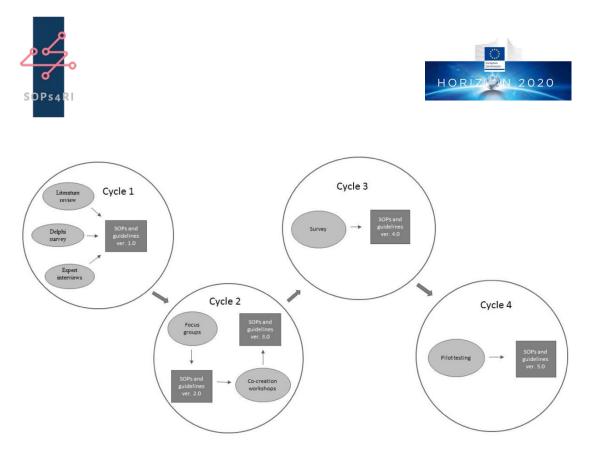


Figure 1: The four development cycles

The first three cycles were designed to provide strong empirical evidence (i.e., literature review, expert reviews, a Delphi survey, focus group interviews, co-creation workshops), with an emphasis on a number of issues and challenges to research integrity: discipline and national related differences, organizational and cultural variances. The knowledge output from those research phases will inform the development of Toolbox 4.0. This version will be further tested in the fourth cycle of research in the SOPs4RI project as pilot tests, to offer a deeper understanding of the key stakeholders' perception of efficiency and effectiveness, as well as of the feasibility of the SOPs and guidelines.

The pilot tests will be the final stage of informing and refining the toolbox – leading to version 5.0.

2.2.1 Theoretical framework for the Pilot Testing

Taking into account the overall goals and ambitions of the project, and translating them into specific tasks for the pilot tests, a community-based participatory research methodology will be introduced as a framework. More recent developments from implementation sciences are also taken into consideration.

Community-based approach

© Copyright by the SORs4RI Consortium





The community-based research approach has its roots in both participatory research and action research. Furthermore, community-based participatory research is 'a collaborative approach that equitably involves all partners in the research process and recognizes the unique strengths that each brings' (Minkler and Wallerstein, 2003:4). It has also been described as a 'systematic inquiry that is collective, collaborative, self-reflective, critical and undertaken by participants (...) that seeks to empower participants and foster social changes' (Rapoport, 1990:499; Bell and Napoleon, 2008:9).

As both action and participatory methods require reciprocal and comparative practices by means of the involvement of the 'researched' party in the choice of research problems, co-development of methodology and community-targeted benefits as a part of the research process, they form an open and inclusive theoretical framework for the pilot testing within WP7.

Implementation science

Implementation science focuses on facilitating and guiding mechanisms and strategies of change for a sustainable uptake of evidence-based interventions. As an emerging and relatively new field, it benefits from a more flexible and non-linear approach ensuring effective translation of evidence into practice (French et al., 2012).

2.2.2 SOP: potential costs and benefits

The SOPs and guideline-toolbox developed in SOPs4RI is a set of instruments each one designed to foster or contribute to the achievement of research integrity. Each SOP and guideline will carry benefits (because of improved research integrity) and costs (implementation and monitoring). The exposure to such costs and benefits will vary across stakeholder groups. Drawing upon the focus groups findings from WP5 and the co-creation workshops in WP 4, Table 1 sets out potential costs and benefits for different stakeholders.

Costs	Stakeholders	Benefits
 Extending effort in completing proposals 	Researchers	 Greater research competence





 Higher quality - slower research pipeline If promotion based on number of publications, lower probability of promotion 		 Greater probability of positive peer review, publications and career progress Access to research grants from agencies that demand RI compliance
 Extending effort in grant application process. Higher quality could cut productivity and slow down the research pipeline 	Research groups	 Higher quality outputs, higher reputation Competitive advantages in research grant applications and in attracting quality research staff Access to research grants from agencies that demand RI compliance
 Monitoring RPOs, research groups and researchers 	Research funding organisation (RFOs)	 Fewer investments in poor quality research Reduction in research waste
 Developing set of SOPs and institutional internal bureaucracy Provision of training programmes Rankings and prestige can be affected negatively (if dependent on number of publications per researcher) 	Research performing organisations (RPOs)	 Fewer cases of FFP and QRPs to address and reduced risk of brand damage More successes to report, heightened reputation





		 Attracting top quality research staff Cost savings from reduced number of investigations by institutions
 Fewer publications per capita leading to potential loss of prestige, rankings etc. 	Nation states and the EU, including policy advisors and policy makers	 Higher quality leading to greater share of highly cited articles Higher confidence in evidence for policy making Possibly better policy decisions
• No apparent costs	The wider public	 Better policies should translate into public good Enhancing trust in science Fighting post-truth, alternative facts etc. Better use of public funds
No apparent costs	Industry	 Better chance of reproducibility leading to diminishing economic costs Enhancing trust in science

Table 1: SOPs and guidelines – plausible costs and benefits by stakeholders





3 Implementation of the objectives of Work Package 7

Implementation strategy

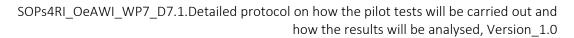
Pilot tests, designed and planned as participatory and co-creational actions, will bring the developed SOPs and guidelines into a real-life setting, in close cooperation with selected pilot institutions: public RFOs (FWF and RCN), private RFOs (La Caixa Foundation and Novo Nordisk Foundation) and four RPOs: Ghent University, Jagiellonian University, University Pompeu Fabra and Janssen Pharmaceutica N.V. (member of EQIPD). The RPOs were sampled based on the following main selection criteria: geographical diversity, representation and inclusiveness of countries, profile diversity, members of European associations and umbrella organisations (The Guild of European Research-Intensive Universities, the European Association of Research Managers and Administrators, EQIPD, etc.).

For this stage of development and refinement of the toolbox, the deciding factor will be the mapping of relevant stakeholders in each pilot institution to interact with and offer guidance and inspiration on all relevant institutional levels.

The pilot testing will establish a dialogue between the SOPs4RI partners and selected key stakeholders within single pilot institutions. The main areas of analysis will be: efficiency and effectiveness of the proposed SOPs and guidelines, co-creating an institution-tailored RIPP, and reflection on experience(s) of the implementation process, including costs and benefits of the implementation. In addition, methods for monitoring the implementation of those proposed guidelines will be developed.

As an additional objective, the shared analysis and testing of SOPs and guidelines, cocreation and implementation of RIPPs, together with an assessment of needs and opportunities, costs and benefits, is expected to develop a movement towards a common vision of responsible research among all stakeholders and participants in the project.

The specific actions and phases of the pilot testing implementation are presented in Figure 2.



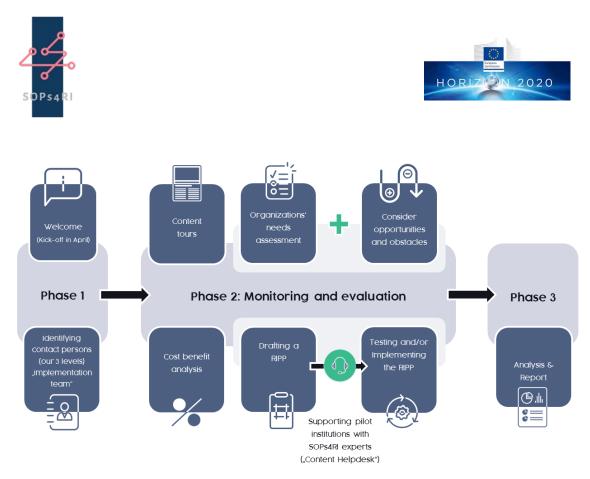


Figure 2: Implementation phases

The final design of the methodology and procedures in the pilot testing of the SOPs and guidelines will not be consolidated before a *reconnaissance* in the pilot sites has been conducted. The reconnaissance will establish (i) what is feasible in the sense of the identification of, and potential access to key stakeholders and informants and (ii) what appear to be the relevant opportunities and constraints to the implementation of the various SOPs and guidelines. The reconnaissance will start with the kick-off meeting with the pilot institutions and will only be completed when the WP7 partners have met the key personnel and have understood what are the institutional governance arrangements relevant to RI. In recognition of the variety of institutions' practices, the reconnaissance will be investigative with the broad objectives of understanding (i) what, if any, are the current RI procedures, (ii) which committees/individuals are responsible? (iii) who would be likely to be interested in leading developments and/or in resisting the introduction of RI procedures? Throughout the reconnaissance members of WP7 implementation team must be sensitive to issues that have not appeared on the agenda of the SOPs4RI study as these may well be of significance.





3.1 Specific objectives

3.1.1 Pilot test of the toolbox (M 24-44, leader: OeAWI, participants: EARMA, KUL, CWTS, NTUA, MEFST, AU, VUmc)

SOPs and guidelines developed in WP4 as version 4.0 of the toolbox will be tested as a pilot in eight institutions. The pilots are designed to evaluate whether the SOPs and guidelines are comprehensive and practical towards the needs and expectations of each institution. Ensuring an effective translation of evidence-based findings into real-world settings may require a revision of earlier steps of the process. This, in turn, will ensure that the final version of the toolbox will be useful and applicable for the intended stakeholders.

Procedure:

The work of WP7 will entail three main phases:

- phase one *planning, designing and informing*,
- phase two *pilot testing* and *cost benefit analysis*
- phase three *analysing and reporting*.

Phase one will consist of the following steps:

In the first step the planning and design of the entire process will start, building on the knowledge gathered previously within the project and the expertise of the consortium members. As already stated, the work of WP7 will be informed by the knowledge output created throughout the first three research cycles of the project. Therefore, a strong cooperation and involvement of the members of respective WPs that contributed to the generation of the empirical validation of the SOPs and guidelines, is planned (i.e., WP3, WP4, WP5). Furthermore, to fulfill the multiple objectives of the pilot testing phase, all partners will participate in specific working groups (Task Forces – see point 2.7). The leading partners of the 'Pilot testing working group' and the 'CBA and Evaluation working group' will be responsible for the further work and tasks' distribution.

The second step will consist of mapping the relevant stakeholders for the creation of 'implementation teams' within each pilot institution. Engaging with the three levels of





internal actors and stakeholders (top management, RI officers/administrators, researchers) is imperative for the achievement of the goals of the pilot testing.

The third step in phase one will be the kick-off meeting end of April with representatives of the pilot institutions (M28) introducing the goals and timeframe for the pilot testing.

Phase two will be the most crucial as it will facilitate and support all main elements and activities of the work within WP7: testing the toolbox, drafting and implementing a RIPP, and the cost-benefit analysis.

The first step will comprise of drafting an implementation guideline. Rather than a specific tool to foster RI, this implementation guideline is envisioned to be a framework and concrete advice to both RPOs and RFOs on how to establish a RIPP and how to implement specific tools from the toolbox. The guideline should be provided as an open and inclusive way of supporting organisations in how to implement the tools and other resources from the Toolbox. The implementation guidelines should introduce a collective reflection tool (i.e., as an inclusive mechanism for engagement, co-creation and feedback), with identified starting points on how to implement proposed action(s) within an organisation's existing RI culture.

The establishment of the implementation guidelines will be based on the large body of existing literature on organisational studies. It will subsequently be informed by the consortium's expertise regarding RI policies and procedures.

The second step will focus on engaging the institutions involved in the piloting phase with the topics identified for RPOs and RFOs through communication with already established groups of experts within WP7. These experts will be responsible for up to two topics, from the very beginning and through the whole process of pilot testing and implementation of tools (*Content Helpdesk*). In this phase, responsible individuals in the pilot testing organisations will get familiarized with the SOPs, guidelines and existing resources and they can give their first feedback on both content and functionality.

First meeting(s) (*Content tours*) will be prepared by *Content Helpdesk* experts responsible for respective topics – as an introductory presentation of the topic, including a state-of-the-art section, and the most recent developments within the project, with a following Q&A session.

The work of **Content Helpdesk** experts will be crucial in establishing connections with the relevant key stakeholders within the pilot institutions, enabling in-depth analysis of the





topics and creating a platform for joint and shared discussion and work between the pilot institutions and the SOPs4RI partners during the whole testing phase.

The third step will start the process of self-assessment with the guidance of the **Content Helpdesk** experts responsible for respective topics. In this phase, the identified general topics for RPOs and RFOs will be translated into a RIPP, acknowledging the organisational culture and environment of each pilot institution. The implementation guideline cocreated in step one will be a starting point, especially in reflecting on potential hurdles in the implementation process of novel tools and ways of overcoming them. The input from the self-assessment phase can additionally inform the cost-benefit analysis.

The work will be organised in smaller groups to offer a more in-depth and contextualized discussion and guidance on the topics for each implementation team in the respective pilot institution. The internal actors and stakeholders in each pilot institution will be asked to reflect on the usefulness of their existing practices as compared to the proposed SOPs and guidelines but also on the feasibility of the planned implementation.

Each SOP or guideline will be checked on the basis of four criteria

- Practical, legal and financial barriers to implementation (Administration);
- Principle, practical and financial barriers to implementation (Researchers or Scientific officers);
- The likelihood that leadership accepts changes and invests in them (Policy Makers);
- Support for change (actively promoting to actively preventing).

In the fourth step, input from working group meetings will enable the 'implementation teams' in the pilot institutions to start drafting the RIPP template to be further consulted, discussed and co-created with the WP7 experts. The drafted RIPP will be the basis for exploring and testing the Toolbox version 4.0 (M34).

In the fifth step, it will be assessed, which of the SOPs and guidelines proofed challenging for the implementation teams, as well as the reasons for these challenges. These may be caused by practical or legal factors but they can also be due to an incompatibility with the organisational culture. It may as well be that some SOPs or guidelines turn out to be undesirable or even unacceptable to key stakeholders.

In the sixth step, a final input to the last version of the Toolbox (version 5) will be created and the RIPP will be finalised. The feedback from the pilot testing phase will further inform and fine-tune the last version of the SOPs and guidelines. Special attention can be given





to input concerning the gaps and limitations of the proposed SOPs and guidelines, topics that are covered by national legal regimes and therefore excluded from soft law mechanism and initiatives, tools not relevant or not acceptable within the organisational culture(s) of the pilot institutions.

Furthermore, the co-created RIPP can serve as a template and add to the contextualisation of the tools developed within the project. Highlighting specific examples can be considered as a possibility for sharing and fostering best practices.

Phase three will consist of an analysis part and reporting. Expected outputs are the deliverable 7.2. "Report on the Pilot Studies" and deliverable 7.3. "Cost-Benefit Analysis". All partners will be involved in the analysis and reporting part, as members of the working groups (Task Forces) within WP7. The coordination, final analysis and writing of the reports will engage three main working groups (Task Forces): 'Pilot testing working group', 'CBA and Evaluation working group' and the 'RIPP template and implementation guideline working group'.

All input gathered during the pilot testing phase will be analysed, taking into consideration the general framework of the project and the input needed for the Toolbox.

3.1.2 Conduct a cost-benefit analysis (M24-44, leader: LSE, participants: UoT, UoW, CWTS, OeAWI, EARMA)

In phase two, this task will analyse respondents' perceptions of costs and benefits of different SOPs and guidelines and the feedback on the same issue from the pilot tests. The aim will be to create a standard CBA report, in line with the method chosen in the cocreation workshops (CCWs) (Deliverable D.4.4) and to develop recommendations for policy options and communication strategies for RPOs and RFOs on the implementation of RIPPs.

The CBA procedure:

In the proposal, the swing method for the assessment of the relative impacts and costs of the 9 topics was set out. A limitation of this method became apparent in the co-creation workshops. While the swing method would be appropriate if the pilot RPO institutions had implemented the 9 RIPP topics and the pilot RFOs had implemented the 6 RIPP topics, the CCWs evidenced considerable heterogeneity in the adoption of RI policies and





practices within and between EU member states. Combining views on current and hypothetical policies might lead to unreliable data.

On the basis of insights from the co-creation workshop it is proposed to employ two versions of the SWOT (strengths, weaknesses, opportunities and threats) type analysis – (i) a post-implementation SWOT and (ii) an anticipatory SWOT. SWOT should be interpreted in flexible fashion and be conducted in a process similar to 'elite semi-structured interviews'. The rationale for the two versions is that some of the pilot institutions will have implemented some/all of the 9/6 broad RI topic areas and others not.

Selection of interviewees

In the selected pilot sites it is possible that people in different roles will be the most relevant for the institutional assessment of the costs and benefits of the various RI topics. Insights from the reconnaissance and the advice of the implementation team will allow for the selection of the most appropriate interviewees in the different pilot sites. The number of interviews in each site may vary between 1 and 4 individuals. Again, the choice will be based on the understanding of the local decision taking environment.

Interview procedures

Selected respondents will be sent an invitation to participate in a study focusing on the costs and benefits of RI procedures in RPOs and RFOs. They will be informed that the interview, either face to face or online, will solicit their opinions on a number of RI issues. The potential respondents will be told (i) that the interview will be recorded for analytic purposes only, (ii) that they can withdraw from the interview at any point (ii) that if they withdraw their data will be excluded from subsequent analyses, and that (iii) they will be assured of anonymity and that their comments/opinions will not be attributed to them in any report. If they agree to be interviewed respondents will be invited to complete an informed consent statement.

Interview type

Given that the interviewees will be experienced professionals and administrators the interview method will follow techniques used in semi-structured elite interviewing. In semi-structured interviews the topic guide sets out the issues to be discussed and gives





the interviewee the time and opportunity to explain or develop a point in their own words and in their own time. The technique also allows the interviewer to ask/probe for further information on points of relevance to the study's objectives and also allows the interviewee to comment on issues that may not have been raised in the topic guide.

The conduct of the interviews

The interviews, designed to last for 60-75 minutes will be conducted by members of the CBA working group, most of whom have experience of face to face depth-interviewing. For those without such experience a training session will be offered by Prof. George Gaskell who has 25 years experience in qualitative research.

In the following paragraphs drafts of a semi-structured interview guide are presented.

Post implementation draft topic guide for research policy makers and RI administrators

The interviewer introduces her/himself Reminder of the study's objectives A broad outline of the topics for discussion Audio recording and informed consent

Topic guide

- Of the nine topics in the RIPP, have you already implemented any of them?
- Which one was the most recent to be implemented?
- What led you (the institution) to implement topic X; what objective(s) had you in mind?
- Who was the driving force in pushing topic X?
- To what extent have those objectives been realised? Did you mount a formal evaluation?
- Did you experience any difficulties implementing topic X?
- Were there any unforeseen consequences of implementing topic X?
- In terms of benefits (if any) what have they been and who have been the beneficiaries?

• What were the resource implications – one off and recurrent - of implementing topic X?

• If another institution were considering implementing topic X what advice would you give them?





Anticipatory SWOT for research policy makers and RI administrators

Following the same introduction as above

Topic guide

- So you are thinking about implementing topic Y
- What led to that decision?
- Who was the driving force in the institution?
- What is the institution hoping to achieve from that?
- What will be the procedure for implementing topic Y, who will be involved?
- How long will it take and what resources will it entail
- Will you be evaluating the impact of topic Y? When and how?

Research ethics

The interview guidelines and procedures for informed consent and data privacy of respondents will be submitted with a description of the rationale of the study to the Research Ethics Committee (REC) of the London School of Economics. Should any ethical concerns be raised by the REC these will be sent to the SOPs4RI Executive Board for consideration and ameliorative action. The study will not commence without the approval of the REC. All reports/opinions of the REC will be lodged in the Project archive.

Analysis of the interviews

The interviews will be audio recorded and transcribed in the language of the respondents. An analytic protocol will be developed by the CBA leaders to ensure that the major currents of opinion regarding the potential benefits and costs of the RI topics are identified. A qualitative text analytic packages, for example NVIVO, will be implemented to facilitate comparative analyses across the different pilot test sites.

Reporting

A synthetic report will pull together the views about the benefits and costs of the RI topics articulated by members of the pilot sites. Particular note will be taken of differences in views between those sites with a long history of engagement with RI and those for whom RI has not featured as a priority.





4 Expected scientific and social benefit of the research

The SOPs4RI-project aims to promote excellent research that aligns with the principles and norms of the ECoC to help RPOs and RFOs foster responsible research practices and counter research misconduct. The project works towards reducing the existing fragmentation and diversification of procedures, guidelines and regulations. As one of the project's ambition is to reach beyond sharing knowledge, the focus is on organisations that are involved in developing, planning, implementing and evaluating SOPs and guidelines.

The aim of the work in WP7 is twofold: to test the developed and empirically informed SOPs and guidelines as a pilot study in selected institutions and to conduct a cost-benefit analysis. Working with key players within the research community will not only provide relevant feedback on the efficiency and effectiveness of the developed SOPs and guidelines to improve and fine-tune the SOPs and guideline-toolbox, but will further contextualise the SOPs and guidelines within the existing science system and research culture(s). The pilots will test how easy it is to implement and use the developed SOPs and guidelines and will provide information on the costs and benefits of these instruments. Without this knowledge and a more practical exposure, we would risk that the toolbox would be too generic and not adaptable to the needs of RPOs and RFOs.

The piloting phase of the SOPs4RI-project will offer benefits for the institutions involved. As both RPOs and RFOs play a crucial role in fostering a strong research integrity culture – as it is recognized and underlined by the ECoC – they can also be the drivers of institutional and/or cultural change in the broader research environment. The cocreational and participatory approach of all planned activities within the testing phase will allow the pilot institutions to proactively identify and fill in gaps in the existing systems and organisational frameworks, to strengthen and promote responsible research. The ambition of WP7 is to encourage the pilot institutions to continue and lead this positive change also after the completion of the work in the SOPs4RI-project.





5 Expected outputs

The expected output of the pilot testing phase is:

- 1) This protocol (deliverable 7.1.)
- 2) Deliverable 7.2. "Report on the Pilot Studies"
- 3) Deliverable 7.3. "Cost-Benefit Analysis"
- 4) One or more published articles in relevant academic journals





6 Data management and privacy

We will ensure that our data management procedures comply with the General Data Protection Regulation (GDPR) of the European Union. Furthermore, the collection and management of data will be performed according to the Data Management Plan of the project (cf. Deliverable D1.2).





7 Contribution of work package partners

The Austrian Agency for Research Integrity (OeAWI) will lead the work in WP7 described above. As the work planned within WP7 consists of many and diverse tasks, six working groups (Task Forces) will be designed in the beginning of the process. All SOPs4RI partners within WP7 will participate in the design and planning phase and in the analysis and writing of the final reports.

The contribution of work package partners is described below:

WP partner	Description of contribution	Months
OeAWI	WP lead. Leading the designing and planning of the test piloting, coordinating the work and communication between all working groups (Task Forces), leading the analysis work for the piloting phase and report writing (D.7.2.). Involved in all working groups (Task Forces), leading the 'Pilot Testing working group' (Task Force).	24
EARMA	Involvement in designing and planning, leading the 'Content Helpdesk working group' (Task Force), member of the 'Pilot testing' and 'Toolbox permanent working groups' (Task Forces).	6
AU	Involvement in designing and planning, leading the 'RIPP template and implementation guideline working group' (Task Force), involved in 'Pilot testing working group' (Task Force).	4
VUmc	Involvement in designing and planning, leading the 'Toolbox permanent working group' (Task Force), member of 'Content Helpdesk working group' (Task Force).	4
MEFST	Involvement in designing and planning, member of three working groups: 'RIPP template and implementation guideline', 'Pilot Testing' and 'Content Helpdesk' working groups (Task Forces).	4





NTUA	Involvement in designing and planning, leading the working group (Task Force) 'Self-assessment and communication', involved in 'Pilot testing' and 'Content Helpdesk' working groups (Task Forces).	4
CWTS	Involvement in designing and planning, member of the 'CBA and Evaluation working group' (Task Force).	4
KUL	Involvement in designing and planning, member in 'Pilot testing' and 'Content Helpdesk' working groups (Task Forces).	4
LSE	Involvement in designing and planning, leading the CBA and the 'CBA and Evaluation working group' (Task Force), leading the analysis work for the CBA and report writing (D.7.3.)	2
UoT	Involvement in designing and planning, member of the 'CBA and Evaluation working group' (Task Force).	2
UoW	Involvement in designing and planning, member of the 'CBA and Evaluation working group' (Task Force).	2





8 References

ALLEA. The European Code of Conduct for Research Integrity, revised edition. Berlin 2017, http://www.allea.org/wpcontent/uploads/2017/04/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf. (last accessed 23.02.2021)

- Castellanet, C. & C. F. Jordan. 2002. *Participatory action research in natural resource management*. New York: Taylor & Francis.
- Deliverable 1.2 Data Management Plan, Standard Operating Procedures for Research Integrity Consortium, Authors: S. Fuglsang, N. Mejlgaard, <u>https://sops4ri.eu/deliverables/</u> (last accessed 21.04.2021).
- Deliverable 4.4 *Report on the Co-Creation Workshops*, Standard Operating Procedures for Research Integrity Consortium, Authors: Daniel Pizzolato, Kris Dierickx, Joeri Tijdink, Iris Lechner, Krishma Labib, Iris Lechner, Noémie Aubert Bonn, Borana Taraj, Nick Claesen, and George Gaskell.
- EU General Data Protection Regulation (GDPR). 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, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1.
- French, S.D. & S.E. Green & D.A. O'Connor DA, et al. 2012. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implementation Science* 7:38. doi:10.1186/1748-5908-7-38 (last accessed 29.03.2021)
- Geertz, C. 1973. The Interpretation of Cultures. Selected Essays. New York: Basic Books.
- Israel, B. & A.J. Schulz & E.A. Parker. 1998. Review of community-based Research: Assessing Partnership Approaches to Improve Public Health. *Ann. Rev. Public Health* 19: 173-202.
- Minkler, M. & N. Wallerstein. 2003. *Community based participatory research for health*. San Francisco, CA: Jossey-Bass.
- Rapoport, R. 1990. Three dilemmas in action research. Human Relations 23(6): 499–514.
- Roundtable on Translating Genomic-Based Research for Health; Board on Health Sciences Policy; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine. Washington (DC): National Academies Press (US); 2016 Jul 6.
- Smith, L. T. 2000. *Decolonizing methodologies: research and indigenous peoples*. New York: Zed Books.
- Wadsworth, Y. 1998. What is participatory action research? *Action Research International*, Paper 2 http://www.scu.edu.au/schools/gcm/ar/ari/p-ywadsworth98.html. (last accessed 21.01.2021).

© Copyright by the SORs4RI Consortium





Whyte, W. F. 1991. Participatory action research. Newbury Park, CA: Sage Publications.





A. Appendix

Preliminary Roadmap for WP7

Planning and designing

Deadline	Task	Partners involved
Deddinie		
M24-M28	Input from WP2, WP4, WP5 and WP6	OeAWI/EARMA/AU/Vumc/NTUA/UoEX
	Expectations of WP4	
M24	Preliminary testing with selected institutions	OeAWI/EARMA
M26	Agenda for the kick-off meeting of WP7	OeAWI
M27	Planning the kick-off meeting of WP7	OeAWI/all
M27	Task distribution between partners	OeAWI/all
M27-M28	First working group meetings	OeAWI/all
M26-M28	Implementation strategy planning and designing	OeAWI/EARMA/all
M27	Implementation Guideline – designing and planning	AU/OeAWI/MEFST
M27	Drafting invitation letter to pilot institutions	OeAWI/EARMA





M26-M36	Documents for target groups (top management, administration/RI officers, researchers):	OeAWI/EARMA/NTUA
	 Documents (leaflets, etc) Online resources (web- based), etc. 	
M28	Deliverable 7.1. ready for review : Protocol for the pilot testing. It will give a detailed description of how the test piloting will be done and how the results will be analysed.	OeAWI/EARMA/AU
M28	Kick-off meeting with piloting partners (Milestone: Pilot implementation kick-off meeting)	OeAWI/EARMA/all
M28	Deliverable 7.1. uploaded to the EC	AU

Pilot Testing

Deadline	Task	Partners involved
M28	Kick-off meeting with piloting partners	OeAWI/EARMA/all
	(Milestone:Pilotimplementationkick-offmeeting)	
M28-M34	Mapping of the stakeholders	OeAWI/EARMA





M28	Recruitment of relevant stakeholders ('implementation teams') process begins	OeAWI/EARMA
M29-M34	Introductory presentation of the topics for RPOs and RFOs (<i>Content tours</i>)	OEAWI/all partners involved
M30	Content Helpdesk open	OEAWI/all partners involved
M30	First draft of Implementation Guideline finalized	AU/OeAWI/MEFST
OPTIONAL	Exercises for pilot testing (case studies, additional resources, etc.)	OeAWI/KUL/AU/CWTS/MEFST
OPTIONAL	Pilot testing guide (guidelines) for partners	OeAWI/EARMA/KUL/AU/MEFST/NTUA/ LSE
OPTIONAL	Finalize design of pilot testing exercises	OeAWI/KUL/CWTS/AU/LSE/NTUA
OPTIONAL	Test of pilot exercises	OeAWI/EARMA/KUL
OPTIONAL	Adjustment of the pilot testing exercises	OeAWI/EARMA/KUL
M31	Recruitment of representatives from target groups per institution finalized	All involved partners





M31	Guidelines for practicalities in connection with the pilot training	OeAWI
M31	Self-assessment of pilot institutions begins	OeAWI/EARMA/all partners involved
M34	Pilot testing of Toolbox version 4.0. period begins	OeAWI, EARMA, KUL, CWTS, NTUA, MFEST, AU, VUmc
M34	Templates/protocols/document s for the CBA send out	LSE/UoT/UoW
M39	Interviews conducted	LSE/UoT/UoW/CWTS/All involved partners
M39	Pilot testing finalized	All

Analysing and reporting

Deadline	Task	Responsible/involved
M40	Analysis strategy finalized and analysis of interviews begins:	LSE/UoT/UoW/CWTS/All involved partners
	 responses to version 4.0 of the SOPs and guidelines 	
	 feedback on efficiency and effectiveness of the SOPs and guidelines 	
M40	CBA Analysis	LSE/UoT/UoW/CWTS
M41	Analysis completed	OeAWI/all involved partners





M42	Writing period for Report on the Pilot Testing.	OeAWI/EARMA/KUL/CWTS/NTUA/MFE ST/AU/VUmc
M42	Writing period for the CBA.	LSE/UoT/UoW/CWTS
M43	Deliverable D7.2. ready for review	OeAWI/comments from partners and reviewers
M43	Deliverable D7.3. ready for review	LSE/comments from partners and reviewers
M44	Deliverable D.7.2. uploaded to the EC	AU
M44	Deliverable D.7.3. uploaded to the EC	AU





The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824481.