SOPs4RI

D1.1: Research Integrity and Quality Assurance Plan

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Editor: M.P. Sørensen

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

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"

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SOPs4RI

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Editor:	Mads P. Sørensen
Version:	1.0
Dissemination Level[1]:	PU
Author(s):	Mads P. Sørensen, Niels Mejlgaard, Maura Hiney
Due date of deliverable:	31st of March 2019
Actual submission date:	25th of March 2019
Start date of project:	01 January 2019
Duration:	48 months
Organisation name of lead contractor for this deliverable:	AU

[1]This 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).

Document metadata

Version	*Date*	*Modification reason*	*Modified by*
0.1	20-12-2018	First draft	Mads P. Sørensen, AU
0.2	16-01-2019	Second draft	Mads P. Sørensen & Niels Mejlgaard, AU
0.3	26-02-2019	Third draft	Mads P. Sørensen, AU; Maura Hiney, HRB; and Niels Mejlgaard, AU (drawing on ideas from the group work at the General Assembly meeting in January 2019)
0.3	22-03-2019	Review	Kris Dierickx, KUL
0.4	25-03-2019	Final draft	Mads P. Sørensen, AU
1.0	25-03-2019	Document submitted	Niels Mejlgaard, AU

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1. Introduction

In the following, the research integrity and quality assurance plan for SOPs4RI is described. The document is based on the principles agreed on in the 'SOPs4RI Consortium Agreement' and 'Grant Agreement Number 824481 – SOPs4RI'. It describes how SOPs4RI will ensure a high standard of research integrity and quality of deliverables by:

- Building on "The European Code of Conduct for Research Integrity" published by ALLEA in 2017 (see section 2 below).
- Building on the expertise, skills and knowledge of a strong consortium with 13 partners in 10 different European countries (see section 3 below).
- Drawing on the expertise and experiences of the international Advisory Board (see section 4 below).
- Actively using the expertise and infrastructure of well-established and respectable private and public Research Funding Organisations and European associations/umbrella organisations (see section 5 below).
- Using a well-designed and comprehensive research and development process (see section 6 below).
- Using an efficient management and governance structure (see section 7 below).
- Using a quality assurance system for deliverables building on peer review (see section 8 below).

2. Research Integrity

2.1 Basic principles

SOPs4RI builds on the principles of *Reliability, Honesty, Respect and Accountability*, as described in "The European Code of Conduct for Research Integrity" published by ALLEA in 2017. This Code articulates the values and norms of responsible research behaviour necessary to maximise the quality and robustness of research outputs, and to counter threats to, and violations of, research integrity.

SOPs4RI will:

- ensure *Reliability* through a comprehensive and well thought through research and development process involving appropriate data, methods and analyses. This process is described in detail in the Grant Agreement and will be summarized below in section 6.
- ensure *Honesty* by the way data is handled – and in the open and transparent way in which the research and development process is carried out and reported. (See section 3 and Deliverable 1.2, the Data Management Plan, for details on how the data management in SOPs4RI will be carried out).
- make *Respect* key in the research and development process – internally towards fellow researchers and collaborators as well as externally in relation to respondents, collaborators, the research community and society in general. SOPs4RI expects every member of the consortium to threat internal and external stakeholders with respect and dignity and high ethical standards will secure the protection of human participants as well as personal data (see section 6 below).
- ensure *Accountability* through the management plan for SOPs4RI and organization of it – and through a comprehensive quality assurance process, as described in section 7 and 8 below.

2.2 Ensuring Good Research Practices

In SOPs4RI, *the individual partner institutions* must make sure that they live up to these guidelines, especially when it comes to establishing a 'Research Environment' that supports research integrity and provides the necessary 'Training, Supervision and Mentoring' of researchers, developers and administrators, who take part in SOPs4RI. It is especially important that junior staff are supported by their institutions and guided by senior members of staff, when carrying out tasks within the SOPs4RI project.

Work Package (WP) *leaders* have, in collaboration with the *Executive Board* (EB), the responsibility for ensuring that appropriate and good 'research procedures' are used throughout the project. WP leaders will make it clear who is responsible at various levels in the WP. That said, all participants have individual responsibility for implementing good research practice in their work.

WP leaders must also make sure that the research and development process comply with ethical standards and regulations within the area.

a. Research Environment

- WP Leaders, in collaboration with their institutions, will promote awareness and ensure a prevailing culture of research integrity in their team by identifying and putting in place processes that foster a good research environment. Such processes should include:
    - Developing or adopting (if already available in their institution) clear policies and procedures on good research practice and on the transparent and proper handling of violations.
    - Open discussion and constructive criticism of research design, methodologies, interpretation of outputs and proper use of resources.
    - Creating an environment in which people feel safe and confident to raise concerns.
    - Creating awareness of the European Code of Conduct and its relevance to the research work.
- WP leaders will ensure that their team has access to the appropriate infrastructures and skills to allow them to implement SOPs4RI's data management plan and to ensure accountability for, and quality assurance of, their outputs.

b. Training, Supervision and Mentoring

- The individual consortium partner must ensure that their team has the necessary training to participate in the work in the different WPs in which they are involved. Key competences that the team should have include:
    - Training in, and a strong understanding of, the principles of research integrity
    - Appropriate research design and methodological training, such that they can bring rigor to their research.
    - Training in the use of relevant analytical tools.
    - Appropriate and adequate training in research ethics to ensure that all concerned are made aware of the relevant codes and regulations.
- Agreement from the outset in consortium teams about how junior staff are going to be supervised and mentored.

- Senior researchers should ensure that they are adequately equipped to act as effective supervisors and mentors to team members.

c. Research Procedures and Safeguards (see Section 6 also)

- WP Leaders and their teams will agree at the outset on the research design, methodology and methods for documentation and storage of research outputs, to accountability and transparency.
- WP Leaders will develop extensive study protocols for each WP that take account of prevailing regulation and legislation, including GDPR, and the state-of-the-art in their area and will take account of, and be sensitive to, relevant differences in age, gender, culture, religion, ethnic origin and social class in the study population.
- WP Leaders will ensure that the research and development processes comply with ethical standards and regulations within their area and where appropriate study protocols will be sent to ethical review boards for approval.
- WP Leaders and their teams will handle research subjects with respect and care, and in accordance with legal and ethical provisions (see Section 6 for a detailed description of approach to ethics).
- Where appropriate, studies will be pre-registered at the OSF (www.osf.io) before data collection.
- WP Leaders and their teams will commit to reporting and publishing results and interpretations of research in an open, honest, transparent and accurate manner, and to respect the confidentiality of data or findings when legitimately required to do so.
- WP leaders and their teams will have due regard for the health, safety and welfare of the community, of collaborators and others connected with their research.
- WP Leaders and their teams will strive to identify and manage potential harms and risks relating to their research.

d. Data Practices and Management

- SOPs4RI's plan for 'data practice and management' is described in detail in an independent document (Deliverable 1.2.) and includes:
    - A commitment to make access to SOPs4RI data as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Re-usable) for data management, after anonymization of all direct and indirect identifiers.
    - Developing a data analysis plan for WPs that involves empirical data.
    - A description of how data can be transferred and stored safely and ethically correct within the project.
    - Ensuring appropriate stewardship and curation of all data and research materials, including unpublished ones, with secure preservation for a reasonable period.

- Providing transparency about how to access or make use of their data and research materials.
- Ensuring that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights.

e. Collaborative Working

- *The researchers, developers and administrators* in SOPs4RI all – as individuals – have responsibility for the integrity of the research and the 'Collaborative Working' process of the project.
- The WP leader is in charge of the work carried out in the WP, but every partner and collaborator has a responsibility for carrying out the research and development in accordance with good practice within the area and in an open and transparent way that will make it possible for peers to judge the quality of the work.
- All collaborators have responsibility for working towards the goals set out in the Grant Agreement of SOPs4RI. Therefore, the WP leaders must ensure that partners participating in the WP are well informed at the beginning of the WP about the goals, the planned research and development tasks as well as the deadlines for the work.
- All partners formally agree at the start of their collaboration on expectations and standards concerning research integrity, on the laws and regulations that will apply, on protection of the intellectual property of collaborators, and on procedures for handling conflicts and possible cases of misconduct.
- All partners are properly informed and consulted about submissions for publication of the research results.

f. Publication and Dissemination

- All authors are fully responsible for the content of a publication, unless otherwise specified.
- Agreement will be sought early in the drafting process on the sequence of authorship, acknowledging that authorship itself is based on a significant contribution to the design of the research, relevant data collection, or the analysis or interpretation of the results. COPE guidelines on authorship will apply.
- Alongside deliverables to the EC, SOPs4RI will also produce a number of scientific papers.
    - SOPs4RI will aim for 2-3 high-profile scientific papers, co-authored by all members of the consortium (named individually, with author order reflecting individual contributions). The plan for these high-profile journal articles will be sent out prior to the second GA meeting in September 2019 by the Project Coordinator (PC) and discussed and finalized at this meeting.

- Besides these high-profile papers, it is up to the partners in the individual WPs to discuss and agree on other relevant publications from the WP. If the partners decide to make separate scientific papers from their WP, it is important to ensure that they are not in conflict with the high-profile papers. The publication plan for the WP is negotiated among the partners at the beginning of the WP. Here, it is also decided who will take lead on the single publications. The publication plan for the single WP must be included in the protocol for the WP.

- WP Leaders and their teams will ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public and in traditional and social media.
- Authors will acknowledge important work and intellectual contributions of others, including collaborators, assistants, and funders, who have influenced the reported research in appropriate form, and cite related work correctly.
- WP Leaders and their teams will disclose any conflicts of interest in the publication of results.
- Authors will issue corrections or retract work if necessary, the processes for which are clear and the reasons are stated.
- WP Leaders and their teams will not withhold data and will consider negative results to be as valid as positive findings for publication and dissemination.
- WP Leaders and their teams will adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal or in any other alternative publication form.
- As described in the Grant Agreement (paragraph 29.2), each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to SOPs4RI's results.

g. Reviewing, Evaluating and Editing (see Section 8)

The quality assurance process within SOPs4RI is based on peer review. The EB must ensure that relevant peers have time to review the single deliverables as well as scientific publications in SOPs4RI. The procedure is described in detail in section 8.

2.3 Research Misconduct and other Unacceptable Practices

The European Code of Conduct defines research misconduct as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results:

- Fabrication is making up results and recording them as if they were real.
- Falsification is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.

- Plagiarism is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

These three forms of violation are considered particularly serious since they distort the research record. There are further violations of good research practice that damage the integrity of the research process or of researchers. In SOPs4RI, violations of good research practice will be handled as follows;

- If a partner, WP leader or an individual collaborator fails to live up to the principles and guidelines set out in this document – or is accused of research misconduct or other unacceptable practices – this can either be reported to the 'Adviser for Aarhus BSS', Professor Birgitte Egelund Olsen, or to the PC, who will be available for consulting and who will contact the relevant authorities, if necessary. The 'Adviser for Aarhus BSS' will also inform the PC, if she has been contacted.
- The 'Adviser for Aarhus BSS' and the PC must secure a fair investigation process and, if necessary, together decide on appropriate sanctions and inform the consortium of decisions.
- In the case of fabrication, falsification or plagiarism the PC must take steps to exclude the researcher and/or partner from the consortium as well as report the research misconduct to the relevant authorities.
- If the case is about unacceptable research practices, the PC must take steps to ensure that the research is redone in a scientifically sound way – and give the researcher(s) a warning.
- If the researcher continues to carry out research in a detrimental way, the PC must make sure that the researcher is removed from the task.

In line with the European Code of Conduct, the following principles need to be incorporated into any investigation process.

Integrity

- Investigations are fair, comprehensive and conducted expediently, without compromising accuracy, objectivity or thoroughness.
- The parties involved in the procedure declare any conflict of interest that may arise during the investigation.
- Measures are taken to ensure that investigations are carried through to a conclusion.
- Procedures are conducted confidentially in order to protect those involved in the investigation.
- Institutions protect the rights of 'whistle-blowers' during investigations and ensure that their career prospects are not endangered.
- General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.

Fairness

- Investigations are carried out with due process and in fairness to all parties.
- Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence.
- Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.
- Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.
- Anyone accused of research misconduct is presumed innocent until proven otherwise.

3. The Consortium behind SOPs4RI

To make high quality products, several elements are needed: good raw materials, relevant tools and machinery, a good working process, and appropriate quality control. The most important raw materials in SOPs4RI are the skills, expertise, and knowledge of the partners. These resources will be key in securing high quality in SOPs4RI's deliverables. The consortium consists of thirteen partners from ten different EU countries. All partners have been carefully selected on the basis of their competencies, methodological skills, and expertise on research integrity together with their experiences and knowledge from related national and EU projects as well as relevant networks and communities. The consortium is listed in Table 1 and the relevant expertise, skills and knowledge of the partners are described in detail in the Grant Agreement.

Table 1: The SOPs4RI-consortium

Partner no.	**Partner short name**	**Partner organisation name**	**Country**
1 (coordinator)	AU	Aarhus University	Denmark (DK)
2	VUmc	Stichting VUmc	The Netherlands(NL)
3	MEFST	University of Split School of Medicine	Croatia (HR)
4	UoEx	University of Essex	United Kingdom (UK)
5	OeAWI	The Austrian Agency for Research Integrity	Austria (AT)
6	NTUA	National Technical University of Athens	Greece (GR)
7	CWTS	Leiden University	The Netherlands(NL)
8	HRB	Health Research Board	Ireland (IE)
9	KUL	Katholieke Universiteit Leuven	Belgium (BE)
10	LSE	London School of Economics and Social Science	United Kingdom (UK)
11	EARMA	European Association of Research Managers and Administrators	Belgium (BE)
12	UoT	University of Trento	Italy (IT)
13	UoW	University of Warsaw	Poland (PL)

4. The Advisory Board

The expertise, knowledge and experiences of an international Advisory Board, will further help SOPs4RI producing high quality deliverables. The Advisory Board (AB) will assist and facilitate the decisions made by the General Assembly. The AB members will participate in the meetings of the General Assembly. The AB will also contribute to the discussions of the Executive Board upon request and the General Assembly, provide expert advice on the quality of the main deliverables and increase the international scope of SOPs4RI. AB members will have no formal decision power in the project but will be asked to discuss and review drafts of core project deliverables and in this way be a valuable quality control body.

The Advisory Board consist of seven persons with expertise in research integrity and the development of Standard Operating Procedures (SOPs) and guidelines (see Table 2):

Table 2*:* The Advisory Board members

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.

5. Collaborating organisations

To test the quality of the SOPs and Guidelines produced in the project, SOPs4RI will actively collaborate with and use the expertise and infrastructure of well-established and respectable private and public Research Funding Organisations and European associations/umbrella organisations. These organisations will help SOPs4RI with 'in vivo' testing of the SOPs and guidelines created in the project. Feedback from the pilot tests on the efficiency and effectiveness of the developed SOPs and guidelines will be used to improve and fine-tune the SOPs and guideline-toolbox that is the main product of SOPs4RI. This will ensure that the final toolbox has a very high quality that will enable Research Producing Organisations and Research Funding Organisations to make effective Research Integrity Promoting Plans. The collaborating organisations are listed in Textbox 1:

Textbox 1: Organisations that will help pilot testing the toolbox

Private RFOs:

- La Caixa Foundation (ES)
- Novo Nordic Foundation (DK)

Public RFOs:

- FWF (Austrian Science Fund)
- RCN (The Research Council of Norway)

European associations/umbrella organisations:

- ENRIO
- EARMA (partner in SOPs4RI)
- The Guild (http://www.the-guild.eu/)
- European Brain Council (EBC)
- European Quality in Preclinical Data (EQIPD)

6. The Research and Development Process

A good work process is key in securing a high standard of deliverables. To achieve high quality outputs in SOPs4RI, a systematic and comprehensive research, development and piloting process has therefore been planned. It will include inputs from relevant stakeholders in the field (see detailed description in the Grant Agreement). SOPs4RI extends over 48 months, allowing enough time to carry out consultation and research, develop a toolbox and test how the development of Research Integrity Promotion Plans (RIPPs) can best be supported by the Standard Operating Procedures (SOPs) and guidelines created in the project. A toolbox with SOPs and guidelines will be the core result of SOPs4RI. At the end of the project period, SOPs4RI will launch a website with the toolbox making it possible for Research Producing Organisations and Research Funding Organisations in Europe to use it and create their own RIPPs.

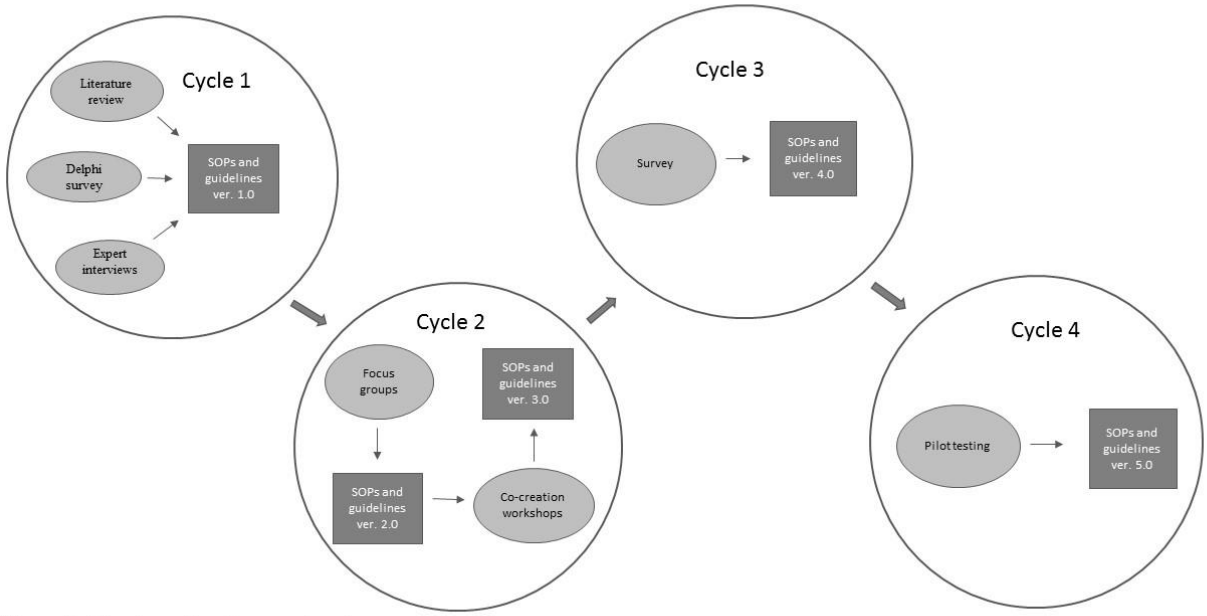


Figure 1: The four development cycles

The project will employ quantitative as well as qualitative methods to collect and process personal data. The storage and handling of data will happen in ways that as far as possible eliminate the risk of confidentiality breaches; comply with legislation on data in the respective countries, and conform to the new EU General Data Protection Regulation (GPDR https://www.eugdpr.org/). Please see deliverable 1.2. (Data Management Plan) for details.

The SOPs4RI will deal with two issues of particular ethical interest: 'Human participants' and 'Personal data collection and/or processing'. As agreed upon in the Grant Agreement, these two issues will be handled in the following way (6.1. and 6.2.):

6.1 Human participants

Before the commencement of research activities involving human participants, the relevant WP leader will submit a statement of research ethics to the Project Coordinator, who will ensure that the research practices are in line with the European Code of Conduct for Research Integrity and Aarhus University's Research Ethics Policy.

The statement and supporting material including study protocol, will account for all ethical issues related to research involving human participants. It will form the basis for the selection and recruitment of participants.

This includes the number of participants, inclusion/exclusion criteria and direct/indirect incentives for participation. A cover letter will be communicated to all participants and thereby ensure that all informants and respondents are duly informed about the scope and purposes of their involvement and the research activities of the project. Moreover, all human participants will be ensured anonymity and confidentiality when appropriate.

Procedures for informed consent will be strictly maintained, and copies of Informed Consent Forms and Information Sheets will be prepared, duly signed, and preserved. These will be concise, and in language and terms understandable to the participants.

Participants will have the right:

- To know that participation is voluntary.
- To ask questions and receive understandable answers before making a decision.
- To know the degree of risk and burden involved in participation.
- To know who will benefit from participation.
- To know the procedures that will be implemented in the case of incidental findings.
- To withdraw themselves, their samples and data from the project at any time.
- To know of any potential commercial exploitation of the research.

The research outlined in this proposal does not intend to involve the collection of sensitive information. It could be anticipated, however, that informants' responses to open questions in the survey or deliberations through focus groups or co-creation workshops might, unintended, reveal sensitive information. Such potential situations will be anticipated in the study protocols and will be submitted for ethical assessment.

Children and adults unable to give informed consent will not be involved in the research.

6.2 Personal data collection and/or processing

'Personal data' is understood as data about an individual who can be identified from that data or from related information. The project partners will respect and strictly adhere to national and

international regulations and laws while conducting research involving human participants and when collecting and processing their personal data. In particular, the partners will respect and strictly abide by the ethical principles expressed in:

- Charter of Fundamental Rights of the European Union.
- Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Directive 2002/58 on Privacy and Electronic Communications.

The project research will be designed according to the new Data Protection Act which was approved by the EU Commission and Council in April 2016 and will come into effect in 2018. Based on this new regulation the data protection of the project will furthermore include the following issues (see D. 1.2. Data Management Plan for further details):

- Access to own data and right to be removed.
- Informing about hacking.
- The use of data for public interest and profiling.
- Privacy by design.
- Responsibilities of the controller and the processor.

In the context of the SOPs4RI project, which will collect personal data and also provide open access to data generated as part of the research project, it is crucial to ensure concise procedures for deleting personal identifiers before offering open access. Responsibilities between the controller of the data and the processor of the data will be clearly defined in a specific Data Protection Agreement to be signed by all partners involved in data collection and processing. The Project Coordinator will be responsible for drafting the Data Protection Agreement. While the project does not expect to collect sensitive data, it is however important to implement strict procedures for safeguarding anonymity whenever this is relevant.

As described in SOPs4RI's Data Management Plan, all data from either individual or social interactions will be dealt with on the basis of two main principles: informed consent and privacy. Photographs, audio and video recordings are personal data and will be handled as such. Participants will be informed at the beginning of interviews of group discussion that video or tape recordings will be used and they will have the option to agree or to decline.

6.3 Ethics Requirements

The following two Ethics requirements will be cleared within the first sixth month of the SOPs4RI's project period:

1. a) The procedures and criteria that will be used to identify/recruit research participants will be submitted as a deliverable. This applies to all human participation in the proposed work,

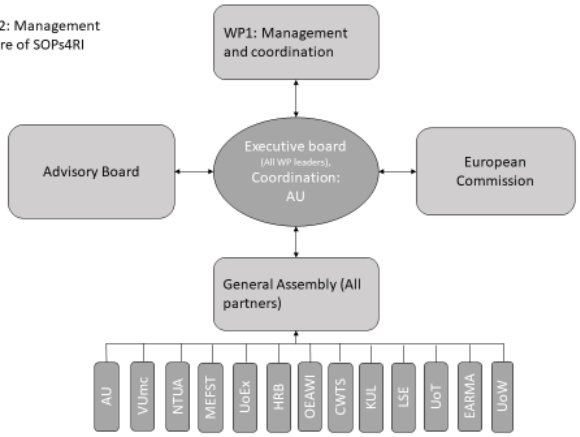
including the on-line surveys. b) Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file.

2. a) The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be kept on file. b) A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable and referred to in the Data Protection Agreements. c) Detailed information on the informed consent procedures in regard to data processing must be kept on file.

7. Management and governance structure

A central part of the work process is the organizational setup (cf. Figure 2). In order to provide high quality deliverables, a complex project such as SOPs4RI, running over four years and involving thirteen partners in ten different countries, requires a transparent and carefully crafted organisational design. To this purpose, a Consortium Agreement (CA), approved and signed by all project partners, has been developed and implemented. The purpose of the CA is to formalise the organisation of the work between project partners, the management of the project, the rights and obligations of the partners. This includes, but is not limited to, their liability and indemnification and to supplement but not conflict with the Grant Agreement. In the following the management structure, organization and responsibilities of the consortium bodies are described as agreed on in the CA.

Figure 2: Management structure of SOPs4RI



7.1 General structure

The organisational structure of the Consortium comprises the following Consortium Bodies:

- The General Assembly as the ultimate decision-making body of the consortium
- The Executive Board as the supervisory body for the execution of the Project, which reports to and is accountable to the General Assembly.
- The Coordinator as the legal entity acting as the intermediary between the Parties and the Funding Authority. The Coordinator, in addition to its responsibilities as a Party, performs the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.
- An Advisory Board with an advisory role and no formal decision power.

a. General operational procedures for all Consortium Bodies

Representation in meetings

Any Party, which is a member of a Consortium Body (hereinafter referred to as "Member"):

- should be present or represented at any meeting;

- may appoint a substitute or a proxy to attend and vote at any meeting; and shall participate in a cooperative manner in the meetings.

Preparation and organisation of meetings

Convening meeting

The Chairperson of a Consortium Body shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
General Assembly	At least once a year	At any time upon written request of the Executive Board or 1/3 of the Members of the General Assembly
Executive Board	At least quarterly	At any time upon written request of any Member of the Executive Board

Notice of a meeting

The chairperson of a Consortium Body shall give notice in writing of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

	Ordinary meeting	Extraordinary meeting
General Assembly	45 calendar days	15 calendar days
Executive Board	15 calendar days	7 calendar days

Sending the agenda

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body a written (original) agenda no later than the minimum number of days preceding the meeting as indicated below.

General Assembly	21 calendar days, 10 calendar days for an extraordinary meeting
Executive Board	7 calendar days

Adding agenda items:

Any agenda item requiring a decision by the Members of a Consortium Body must be identified as such on the agenda.

Any Member of a Consortium Body may add an item to the original agenda by written notification to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

General Assembly	14 calendar days, 7 calendar days for an extraordinary meeting
Executive Board	2 calendar days

- During a meeting the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda
- Meetings of each Consortium Body may also be held by teleconference or other telecommunication means.
- Decisions will only be binding once the relevant part of the Minutes has been accepted according to 'Minutes of meetings' (see below).
- Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document, which is then agreed by the defined majority (see 'Voting rules and quorum' below) of all Members of the Consortium Body. Such document shall include the deadline for responses.
- Decisions taken without a meeting shall be considered as accepted if no Member has sent an objection in writing to the chairperson within 15 calendar days after the written notification. The decisions will be binding after the chairperson sends to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

Voting rules and quorum

- Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the

chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. lf in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented

- Each Member of a Consortium Body present or represented in the meeting shall have one vote.
- A Party which the General Assembly has declared according to Section 4.2 in the Consortium Agreement (on 'Breach') to be a Defaulting Party may not vote.
- Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

Veto rights

- A Member which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.
- When the decision is foreseen on the original agenda, a Member may veto such a decision during the meeting only.
- When a decision has been taken on a new item added to the agenda before or during the meeting, a Member may veto such decision during the meeting and within 15 calendar days after the draft minutes of the meeting are sent. A Party that is not a Member of a particular Consortium Body may veto a decision within the same number of calendar days after the draft minutes of the meeting are sent.
- When a decision has been taken without a meeting a Member may veto such decision within 15 calendar days after written notification by the chairperson of the outcome of the vote.
- In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all its Members.
- A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.
- A Party requesting to leave the consortium may not veto decisions relating thereto.

Minutes of meetings

- The chairperson of a Consortium Body shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 10 calendar days of the meeting.

- The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.
- The chairperson shall send the accepted minutes to all the Members of the Consortium Body and to the Coordinator, who shall safeguard them. If requested the Coordinator shall provide authenticated duplicates to Parties.

7.2 Specific operational procedures for the Consortium Bodies

General Assembly

In addition to the rules described under 'General operational procedures for all Consortium Bodies' above, the following rules apply:

Members

The General Assembly shall consist of one representative of each Party (hereinafter General Assembly Member)

Each General Assembly Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters (listed under 'Decisions' below).

For the avoidance of doubt, any change to the Consortium Agreement or any budget-related change to Annex 1 to the Grant Agreement shall only be legally binding between the Parties if agreed in writing and executed by the duly authorised signatories of each Party.

The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise in a meeting of the General Assembly.

- The Parties agree to abide by all decisions of the General Assembly. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

Decisions

The General Assembly shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. In addition, all proposals made by the Executive Board shall also be considered and decided upon by the General Assembly.

The following decisions shall be taken by the General Assembly:

Content, finances and intellectual property rights

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Funding Authority
- Changes to the Consortium Plan

- Modifications to Attachment 1 to the Grant Agreement (Background lncluded)
- Additions to Attachment 3 to the Grant Agreement (List of Third Parties for simplified transfer according to Section 8.2.2 in the Consortium Agreement)
- Additions to Attachment 4 to the Grant Agreement (ldentified Affiliated Entities)

Evolution of the consortium

- Entry of a new Party to the consortium and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the consortium and the approval of the settlement on the conditions of the withdrawal
- ldentification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
- Declaration of a Party to be a Defaulting Party Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the consortium and measures relating thereto
- Proposal to the Funding Authority fora change of the Coordinator Proposal to the Funding Authority for suspension of all or part of the Project
- Proposal to the Funding Authority for termination of the Project and the Consortium Agreement

Appointments

On the basis of the Grant Agreement, the appointment if necessary of:

- Executive Board Members
- Members of the Advisory Board

Executive Board

b. In addition to the rules in 'General operational procedures for all Consortium Bodies' (see above), the following rules shall apply:

Members

The Executive Board shall consist of the Coordinator and the Parties appointed by the General Assembly.

The Coordinator shall chair all meetings of the Executive Board, unless decided otherwise by a majority of two-thirds.

Minutes of meetings

Minutes of Executive Board meetings, once accepted, shall be sent by the Coordinator to the General Assembly Members for information.

Tasks

The Executive Board shall prepare the meetings, propose decisions and prepare the agenda of the General Assembly

The Executive Board shall seek a consensus among the Parties.

The Executive Board shall be responsible for the proper execution and implementation of the decisions of the General Assembly.

The Executive Board shall monitor the effective and efficient implementation of the Project.

In addition, the Executive Board shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, it necessary, propose modifications of the Consortium Plan to the General Assembly.

The Executive Board shall:

- support the Coordinator in preparing meetings with the Funding Authority and in preparing related data and deliverables
- prepare the content and timing of press releases and joint publications by the consortium or proposed by the Funding Authority in respect of the procedures of the Grant Agreement Article 29.
- develop and implement a plan for monitoring and evaluation of Project progress.
- monitoring research progress in the single work packages.
- coordinate the research and development activities.
- monitor Project milestones and make sure that high quality outputs are delivered on time.
- establish quality standards for the deliverables and organise internal review processes.
- quality check deliverables before releasing them to the Funding Body

In the case of abolished tasks as a result of a decision of the General Assembly, the Executive Board shall advise the General Assembly on ways to rearrange tasks and budgets of the Parties concerned. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled.

c. Coordinator

The Coordinator shall be the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations
- keeping the address list of Members and ether contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Funding Authority
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Funding Authority and fulfilling the financial tasks
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

Before sending any proposal for amendment to Grant Agreement to the EC on behalf of the Parties, the Coordinator will present the documents in question to the Parties and receive their explicit accept which shall not be unreasonably withheld. The terms and conditions of the signed documents are only binding for the Parties if their explicit accept have been given prior to the time of the signature.

lf one or more of the Parties is late in submission of any project deliverable, the Coordinator may nevertheless submit the other 'Parties' project deliverables and all other documents required by the Grant Agreement to the Funding Authority in time.

lf the Coordinator fails in its coordination tasks the General Assembly may propose to the Funding Authority to change the Coordinator.

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

8. The Quality Assurance Process for deliverables in SOPs4RI

As described in the Grant Agreement, SOPs4RI must submit the following deliverables to the European Commission during the project period:

Deliv-erable Num-ber	Deliverable Title	WP no.	Lead beneficiary	Type	Dissemination level	Due Date (in months)
D1.1	Research Integrity and Quality Assurance	WP 1	1 - AU	Report	Public	3
D1.2	Data Management Plan	WP 1	1 - AU	ORDP: Open Research Data Pilot	Public	6
D2.1	Events	WP 2	6 - NTUA	Report	Public	3, 12, 24, 36, 48
D2.2	Analysis and strategy of dissemination	WP 2	6 - NTUA	Report	Public	4
D2.3	Project website and Social Media sites	WP 2	6 - NTUA	Websites, patents filling, etc.	Public	4
D2.4	Brochures and leaflets	WP 2	6 - NTUA	Report	Public	12, potentially 24, 36, 48
D2.5	Online toolbox integrated with SINAPSE	WP 2	6 - NTUA	Websites, patents filling, etc.	Public	48

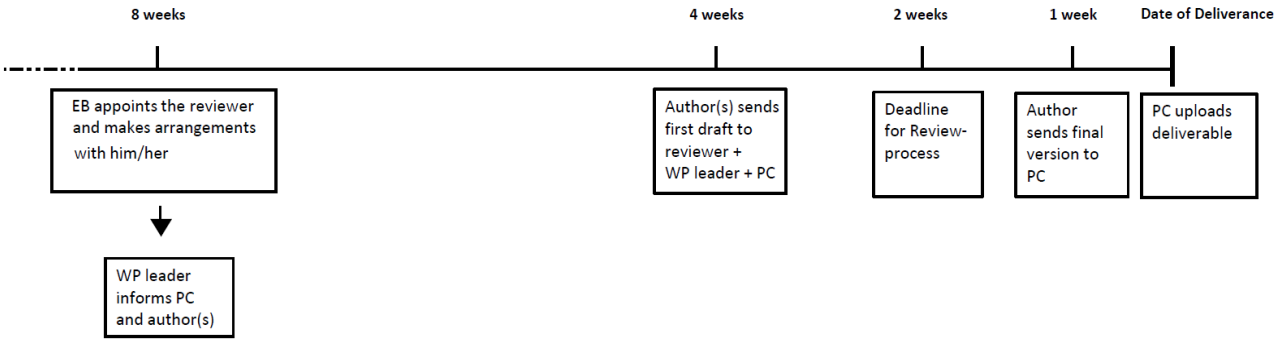
D3.1	Protocol for the literature review, the expert interviews and the Delphi procedure	WP 3	3 - MEFST	Report	Public	2
D3.2	Scoping reviews	WP 3	3 - MEFST	Report	Public	7
D3.3	Report on results of the explorative interviews	WP 3	3 - MEFST	Report	Public	7
D3.4	Report on the rounds of the Delphi procedure	WP 3	2 - STICHTING VUMC	Report	Public	10
D4.1	Protocol for the development of SOPs and guidelines	WP 4	2 - STICHTING VUMC	Report	Public	8
D4.2	First version of the SOPs and guidelines	WP 4	2 - STICHTING VUMC	Report	Public	13
D4.3	Second version of the SOPs and guidelines	WP 4	2 - STICHTING VUMC	Report	Public	21
D4.4	Report on the co- creation workshops	WP 4	9 - KU Leuven	Report	Public	28
D4.5	Third version of the SOPs and guidelines	WP 4	2 - STICHTING VUMC	Report	Public	26
D4.6	Fourth version of the SOPs and guidelines	WP 4	2 - STICHTING VUMC	Report	Public	34

D4.7	Final toolbox with SOPs and guidelines (version 5.0)	WP 4	2 - STICHTING VUMC	Report	Public	48
D5.1	Protocol for the focus	WP 5	1 - AU	Report	Public	13
D5.2	Report on the results of the focus group interviews	WP 5	1 - AU	Report	Public	20
D6.1	Protocol for survey study	WP 6	4 - UESSEX	Report	Public	23
D6.2	Final report and	WP 6	4 - UESSEX	Report	Public	36
D6.3	Cleaned dataset	WP 6	4 - UESSEX	Other	Public	36
D7.1	Protocol on how the pilot tests will be carried out and how the results will be analysed	WP 7	5 - OEAWI	Report	Public	28
D7.2	Report on Pilot Studies	WP 7	5 - OEAWI	Report	Public	44
D7.3	Cost-Benefit Analysis	WP 7	10 - LSE	Report	Public	44
D8.1	H - Requirement No. 1	WP 8	1 - AU	Ethics	Confidential, only for members of the consortium (including the Commission	6
D8.2	POPD - Requirement No. 2	WP 8	1 - AU	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6

8.1 The quality assurance process

The final quality control will take place via a peer review process. No deliverable in SOPs4RI will be submitted to the European Commission without it having undergone a thorough review process where a suitable external or internal reviewer has commented on it, made suggestions for improvements, and where the author(s) in dialogue with the WP leader have adjusted the deliverable according to the review and recommendations. The process is illustrated in Figure 3:

Figure 3: The quality assurance process for deliverables in SOPs4RI



This means that the author must finish a first version of the deliverable four weeks ahead of the date of deliverance. To secure a smooths review process, it is the responsibility of the EB to make sure that a qualified reviewer is appointed at least eight weeks ahead of deliverance and to inform the authors about the name and contact details. The review process will be open and the names of the reviewers will be listed on the deliverables.

The EB will at its second meeting in June 2019 finalize a plan for preferred reviewers for all deliverables from SOPs4RI. The reviewers will typically be other members of the consortium or members of the advisory board, but also other experts can be used as reviewers if the EB finds this necessary. The PC will be informed about the appointment through the EB and must be kept up-to-date through the peer review process. It is the PC's responsibility to upload the deliverable on time.

As for implementing potential revisions suggested by the reviewer, the PC will act as the editor and will have the final say, but in collaboration with the author of the deliverable and with the acceptance of the WP leader.

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SOPs4RI

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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.