Mapping Normative Frameworks of

EThics and Integrity of REsearch

Stakeholder Consultation: Protocol

WP 2 Stakeholder Consultation: Protocol

Project details	
Project:	Mapping Normative Framework of EThics and Integrity of REsearch
Project acronym:	EnTIRE
Project start date:	01.05.2017
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Project number:	741782
Project Coordinator:	Vrije Universiteit Medisch Centrum (VUmc) Amsterdam

Deliverable details	
Work Package:	WP 2 stakeholder consultation
Deliverable description:	Protocol for the phased multi-country stakeholder consultation
Work package leader:	Vrije Universiteit Medisch Centrum (VUmc) Amsterdam
Responsible for the deliverable:	Natalie Evans
Submission date:	31.07.2017

Contents

About EnTIRE

The areas of Research Ethics and Research Integrity (RE+RI) are rapidly evolving. In the EU and internationally, new legislation, codes of conduct and good practices are constantly being developed. New technologies, complex statistical methods, pressure to publish and obtain grants, and growing emphasis on stakeholder driven science (e.g. public-private partnerships) increase the complexity of conducting science (Crocker and Cooper 2015, Nosek et al. 2015). In this complex and dynamic environment, researchers cannot easily identify the correct professional rules (such as codes and guidelines) and best tools (including teaching, expert advice, and analysis of cases) for responsible conduct of research.

The EnTIRE project aims to create an online platform that makes the normative framework governing RE+RI (including rules as well as tools) easily accessible, supports its application in research and evaluation, and involves all stakeholders in a participatory way. Indeed, participation is essential in order to understand the specific needs of stakeholders from different sectors, research disciplines and countries.

About the participatory approach

A central element of the EnTIRE's approach is the iterative, 'bottom up' participatory approach, as illustrated in Figure 1. EnTIRE includes stakeholders' priorities and perspectives, elicited in a **stakeholder consultation**, both in relation to the boundaries of the data to be collected for the online platform and in the online platform's design and development.

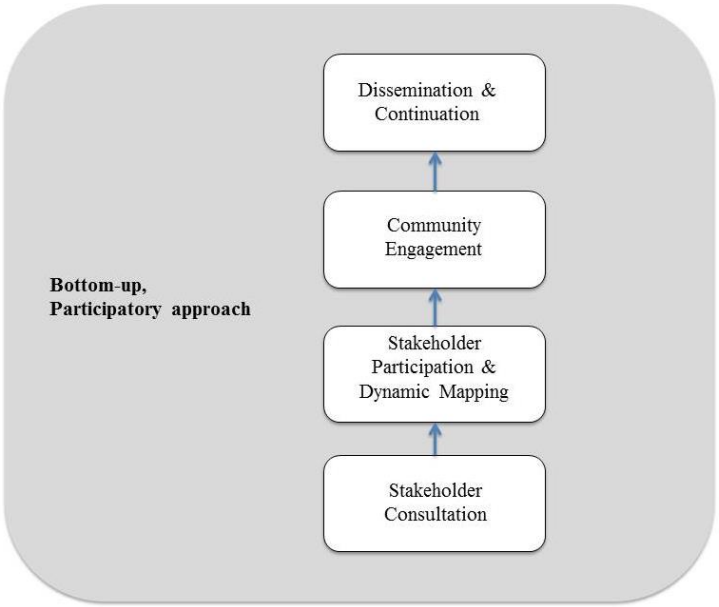


Figure 1. Bottom-up participatory approach

The information made available on the project's online platform will be edited and continuously updated and amended by a community of users (following a wiki approach). This community is developed in part by the stakeholder consultation and further developed by **community engagement**. The constantly evolving online content represents a **dynamic map** of the normative framework for RE+RI, one that is constantly kept up-to-date through community participation.

Intensive participation of a diversity of stakeholders from across Europe is key to the project's success; a sense of ownership amongst stakeholders and their associated networks will result in an online community that will make the platform self-sustainable. The plan for the **continuation** of the platform after the project's end involves its continued maintenance by a community of users who will carry on creating, editing and moderating content.

About the stakeholder consultation

The participatory approach is underpinned by the stakeholder consultation. The consultation will enable identification of the RE+RI issues of concern to the stakeholders, practical experience with regulations and guidelines and other professional, institutional and national norms, resources, and existing best practices. The consultation will also be used to generate, and to reflect on, instructive cases from local practice. The findings from the consultation will help define the boundaries of content to be collected and structure the information on the platform according to stakeholders' concerns; enabling the collection, provision and presentation of data sensitive to stakeholder needs. The process will also foster an ongoing dialogue on the content, priorities, data structure, and acceptability and usability of the platform by the stakeholders.

Aim and objectives

The aim of the stakeholder consultation is to undertake an in-depth exploration of RE+RI experiences and practices across the EU, define the RE+RI normative framework (rules and tools to be collected), and develop a mapping structure adapted to user needs.

Sub-objectives include to:

1. Identify, include and engage a diversity of stakeholders. First, in face-to-face focus groups, and, subsequently, in online focus groups.
2. Explore stakeholders' experiences and perspectives regarding RE+RI, including implicit rules and practices and local cases.
3. Explore additional categories of information that may need to be collected in order to support all stakeholders' informational needs.
4. Define the boundaries of the data to be collected.
5. Provide guidance to the WPs collecting the data for the online platform and the platform developer (WP6) on the diversity of informational needs across the EU and how to adapt the depth and breadth of data collection and online presentation to best reflect diverse user needs.

Preparation

A number of other relevant EU funded projects on RE+RI have also undertaken stakeholder consultations, Appendix 1. We do not wish to replicate the efforts of previous and ongoing EU RE+RI projects. The first step towards preparing the stakeholder consultation is, therefore, to review the findings of previous stakeholder consultations that have been made public, and liaise with the researchers involved in consultations that are ongoing.

Design

The stakeholder consultation takes a qualitative approach; involving face-to-face and online focus groups, and a short questionnaire collecting basic socio-demographic information and participants' background and experience with RE+RI. The participatory and iterative design develops a dialogue with stakeholders over various rounds of focus groups, explores in-depth their experiences, and jointly identifies their informational needs.

Setting

The countries included in the pilot phase are: the Netherlands, Spain, and Croatia. These were chosen to represent three different kinds of countries within the EU; a founding member (the Netherlands), a southern European country (Spain) and new EU member country (Croatia). They also represent a continuum in regard to research and innovation activities and consequently the importance given to RE+RI: according to the European Innovation Scoreboard (http://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards_en), the Netherlands is an Innovation Leader Country (summary innovation index 129.5), whereas Spain is a Moderate Innovator Country (summary innovation index 78.3), with some of the regions belonging to Strong Innovator Regions, and Croatia, as a country in post-communist economic transition, is at the bottom of the group of Moderate Innovator Countries (summary innovation index 54.8). Other EU countries will be included in the online phase of the consultation.

Stakeholders

The consultation will include all major stakeholders in the research process. Table 2 details the target stakeholder groups, diversity within groups and recruitment strategy.

In addition to being a member of one of the identified stakeholder categories, criteria for inclusion in the stakeholder consultaion are:

- Participants are currently active in some stage of the research process (e.g. research, publishing, policy, research funding)
- Participants are over 18 years old
- Proficiency in English language

For both the face-to-face and online focus groups, we aim to recruit the following participants in each of the three pilot countries: researchers from various disciplines [biomedical, social sciences, natural sciences, applied sciences] (4), journal editors (2), members of national and RE+RI committees (4), policy makers (2), representatives from industry, including pharmaceutical companies (2), and representatives from research funding organisations (2). Two groups of eight participants will be formed using these stakeholders. Due to limits on the number of people who can participate in each focus group discussion, it will not be possible to recruit representatives from all sub-divisions of the stakeholder groups (Table 1), however attempts will be made to represent these sub-divisions at the level of the entire consultation – in addition to other intersecting characteristics such as nationality, gender and age. The participant characteristics will be recorded and targeted recruiting will be used to ensure an appropriate mix of stakeholders. In this stakeholder consultation, however, the study does not seek to be fully representative, but rather to include a broad representation of people and disciplines.

Stakeholder category	Sub-divisions	Targeted recruitment strategy
Researchers	Discipline Biomedicine Social sciences Natural sciences Applied sciences	Researchers from a diversity of disciplines will be identified from institutional websites and directly approached and invited to participate.
	Seniority PhD student Research Associate Assistant Professor Professor Head of Department	Researchers with an interest in RE+RI issues and senior researchers will be identified from the literature via online searches and through expert contacts and directly approached and invited to participate.
	RE+RI experience Research interest in RE+RI No expressed research interest in RE+RI	Researchers with an interest in RE+RI issues and senior researchers will be identified from the literature via online searches and through expert contacts and directly approached and invited to participate.Researchers without an expressed interest in RE+RI issues, Junior Researchers and PhD Students will be recruited via an English language advert in their institution's digital newsletters, via department mailing lists and disseminated on discipline specific twitter feeds and blogs.
	Sector Academia Industry	Researchers working in industry will be recruited via industry contacts and industry specific twitter feeds and blogs.
Journal editors and assistant editors	Journal disciplines Biomedicine Social sciences Natural sciences Applied sciences	Journal editors will be identified with the help of COPE (the Committee on Publication Ethics) and invited to participate. COPE is a platform for publishers and journal editors. Dr. Elizabeth Moylan is a Council member for COPE and member of the Advisory Board of EnTIRE. This will facilitate COPE's cooperation
RE+RI committees	Geographical scope National Local Institutional	National, local and institutionalRE+RI committee members will be identified with the help of the European Ethics and Research Integrity Network (ENERI) and invited to participate. ENERI has offered to provide network contacts, expertise, website and communication channels for dissemination of EnTIRE's activities. ENERI coordinator Prof. Dirk Lanzerath is a partner in EnTIRE, which will facilitate ENERI's cooperation. Research Integrity Officers will also be identified with the help of The European Research Integrity Officers (ENRIO). Dr Nicole Foger, a member of EnTIRE's scientific advisory committee, is the chair of ENRIO. In addition, we can draw on the network of contacts from RE+RI committees and insitutional and national policy makers previously developed of Prof. Kris Dierckx (WP3 lead) whilst working on a project exploring heterogeneity concerning research integrity guidance in the European Economic Area.
Policy makers	Geographical scope National Local Institutional European	Policy makers will be identified with the help of ENERI, In addition we can draw on Prof. Kris Dierckx's network of contacts. EnTIRE is also in close contact with Dorian Karatzas (Head of the EC Ethics and Research Integrity Sector). This cooperation will help us identify the relevant people at a

		national, local, institutional and EU level to invite to participate in the study.
Research policy, training and compliance officers from research intensive industries	Research intensive industry Engineering Biotechnology Nanotechnology Pharmaceutical Chemical and Materials science Electronics Aerospace Automotive	Research policy, training and compliance officers from research intensive industries, including pharmaceutical companies, will be recruited via an advert disseminated with the help of contact persons through their organisation's digital newsletters (if possible) and on industry/role specific twitter feeds and blogs. We will also directly approach these stakeholders via the relevant industrial associations (e.g. corporate compliance [http://www.corporatecompliance.org/]; the European Federation of Pharmaceutical Industries and Association [www.efpia.eu/]; and the European Business Ethics Network [www.eben-net.org]).
Research funding organisations	Geographical scope European National Domain Biomedical Social sciences Natural sciences Applied sciences	Country experts, identified with the help of ENERI, ENRIO and Prof. Kris Dierckx's network of contacts, will help us identify and invite members of national research funding organisations covering a range of research domains. Dr. Maura Hiney, a member of EnTIRE's scientific advisory committee, also has substantial knowledge about major European research funders from positions in ALLEA and Science Europe. Dorian Karatzas (Head of the EC Ethics and Research Integrity Sector) – will help us identify the relevant people at an EU level to invite to participate in the study.

Table 1. Stakeholder analysis

Potential participants will be sent an information sheet about the project and the consultation (Appendix 2). On agreeing to participate, they will be sent a short online questionnaire asking questions about basic socio-demographic information: gender, age, role [depending on the stakeholder group – e.g. academics will be asked their area of expertise (biomedical, social sciences, natural sciences, applied sciences) and position (PhD student, Research Associate, Assistant Professor, Professor, Head of Department)], years of experience, nationality and country of residence. The questionnaire will also include a few open questions asking participants what they understand of RI, what RE+RI support is currently available to them, and what they would like to see available but is currently lacking (Appendix 3). They will also be sent informed consent and confidentiality agreements via email (Appendix 4). The questionnaire, informed consent and confidentiality agreements need to be completed before participation in either the face to face or online focus groups.

The consultation occurs in two phases: a pilot, face-to-face stage, and a scale-up online phase (see Figures 2 and 3). Both phases involve 2-3 rounds of discussions with the same participants.

Pilot phase: face-to-face focus groups

The pilot focus groups will take a traditional face-to-face format. Sixteen stakeholders (two groups of eight participants) from each of the three countries (48 in total) will participate in two rounds of focus groups (Figure 2). Additionally, a selection of participants from each country will be selected to take part in a third, multi-country focus group in Amsterdam to discuss similarities and differences between countries. Because the multi-country focus group will be conducted in English, proficiency in English is a requirement and the language of all of the focus groups will be English.

The first focus group will take 2.5 hours, and focus on participants' perspectives and experiences of RE+RI issues. The discussion will be moderated by a researcher from the VUmc (Natalie Evans) and by an additional researcher from the in-country institute (Coosje Veldkamp, Ana Marusic or Emanuele Valenti) who will act as the reporter. A broad exploration of the topic amongst a diverse group of stakeholders will allow us to develop insights into participants' understanding of RE+RI, their experiences and perspectives, and how they can be supported, specifically in regard to their informational needs. Due to the exploratory nature of this first round, which aims to generate new insights and knowledge, a traditional focus group design is appropriate (Stewart et al 1990 pp 122). During the focus group discussions, the reporter will write the main topics discussed on a flip chart. At the end of the focus group, the participants will be asked to categorise these topics using the preliminary data collection categories. This categorization exercise will allow us to identify if any additional data collection categories and efforts are needed.

In the second round, conducted shortly after the first (ideally a fortnight, depending on participants' availability and the time needed for a preliminary analysis of the first round), the same stakeholders (2 x 8 people) participate in a more structured discussion. This will

start with feedback on the themes identified from the previous session, followed by a presentation of a pilot version of the website and a discussion of the preliminary data collection categories of: guidelines, codes, legislations, and standards; committees, training courses and expert advice and contacts; and cases, casuistry and scenarios. The group will be asked to try to navigate the pilot website in pairs on one of four iPads provided. They will then reconvene and provide their feedback regarding the website (in terms of design, usability, structure and content). This session will also introduce the feature for providing feedback on the platform's content and form the basis for the iterative process of platform acceptability and usability assessment.

The third round will bring together, in Amsterdam, a selection of Dutch, Croatian and Spanish stakeholders (who participated in rounds one and two in their own countries) to discuss the preliminary normative framework and the similarities and differences between countries. This round will provide us with an understanding of the diversity of informational needs across the three countries, how to adapt the depth and breadth of data collection depending on the country specific context, and how to adapt online presentation of content to reflect those needs. This third round will take the form of a day long workshop in which the participants help translate the normative framework and the country specific considerations into the website content and design.

The preliminary focus group guides for all three rounds can be found in Appendix 5, however these may be adapted to explore additional themes that arise in previous or parallel rounds, as well as the findings of previous and ongoing stakeholder consultations for other EU funded RE+RI projects (Appendix 1). If some stakeholder groups are not represented in the pilot face-to-face focus groups in any round (e.g. policy makers, journal editors), individual members of the unrepresented groups will be approached to provide their views. They will be asked questions from rounds 1 and 2 of the focus groups in one session.

Scale-up phase: online focus groups

The scale-up phase will take the more novel approach of online focus groups. These will cover similar content as the face-to-face focus groups but in an online format (Figure 3). An online approach is appropriate due to the spread of participants across Europe and the logistical difficulties in planning face-to-face sessions in all European countries (Rezabek et al., 2000). Online focus groups have also been show to elicit similar content to face-to-face focus groups (Woodyatt et al. 2016) and online methods may even be better for eliciting information about less socially desirable experiences and attitudes (Woodyatt et al. 2016, Schiek and Ullrich 2017). As such, the online focus groups, in which participants interact anonymously, might complement the data derived from the face-to-face interviews by better exposing deviant experiences or attitudes related to research misconduct. The rounds of discussions will be the same as for the face-to-face focus groups and the language of the discussions will be English.

Online focus group procedure

Stakeholders who have been invited to participate in the online discussions, or who respond to the recruitment advertisement, will be sent a link to join a closed online focus group, their login name and password. Participants will be informed of the start date of the discussion. Questions will be posted every two days and participants will receive email notifications about new questions. These questions will have been refined as a result of the face-to-face focus groups. Participants will be able to contribute to the discussion thread at any time over a two week period. During that time, the moderator will also be informed by email if a participant has posted a response and can post follow-up questions to further probe any issues raised and elicit more in-depth material. To encourage interactions, participants will also receive emails to inform them when other participants have contributed to the discussion.

Due to the challenges in recruiting a diversity of stakeholders from each EU country, the researchers may change the online approach from online focus groups for each country to multi-country online community discussions depending on stakeholder response. Multi-

country community discussions might be preferable in order to ensure a good stakeholder mix if response is poor, particularly if recruitment is found to be difficult in some countries, and responses can still be compared depending on participants' country of residence.

Figure 2. Pilot phase: Face-to-face focus groups

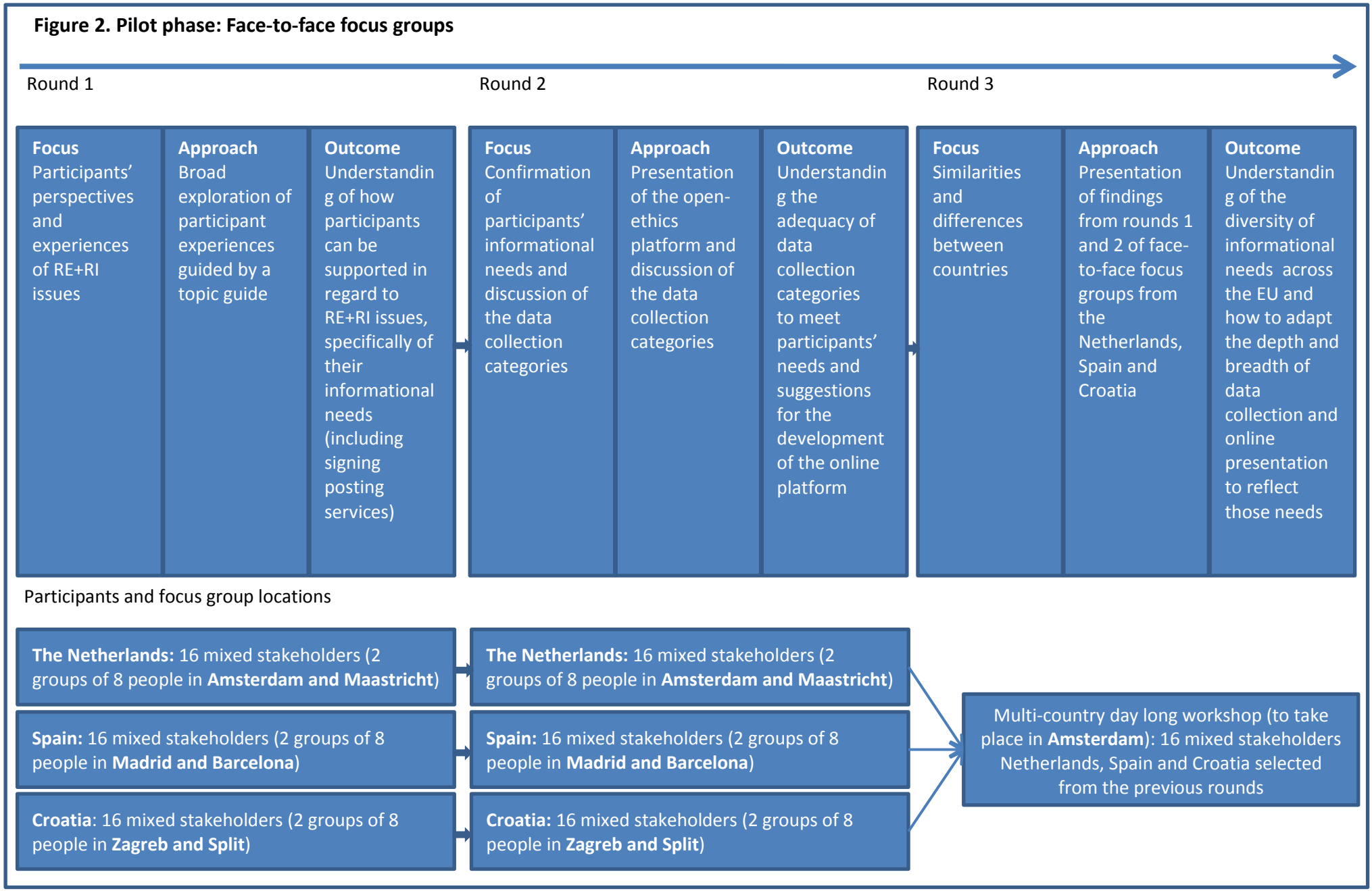
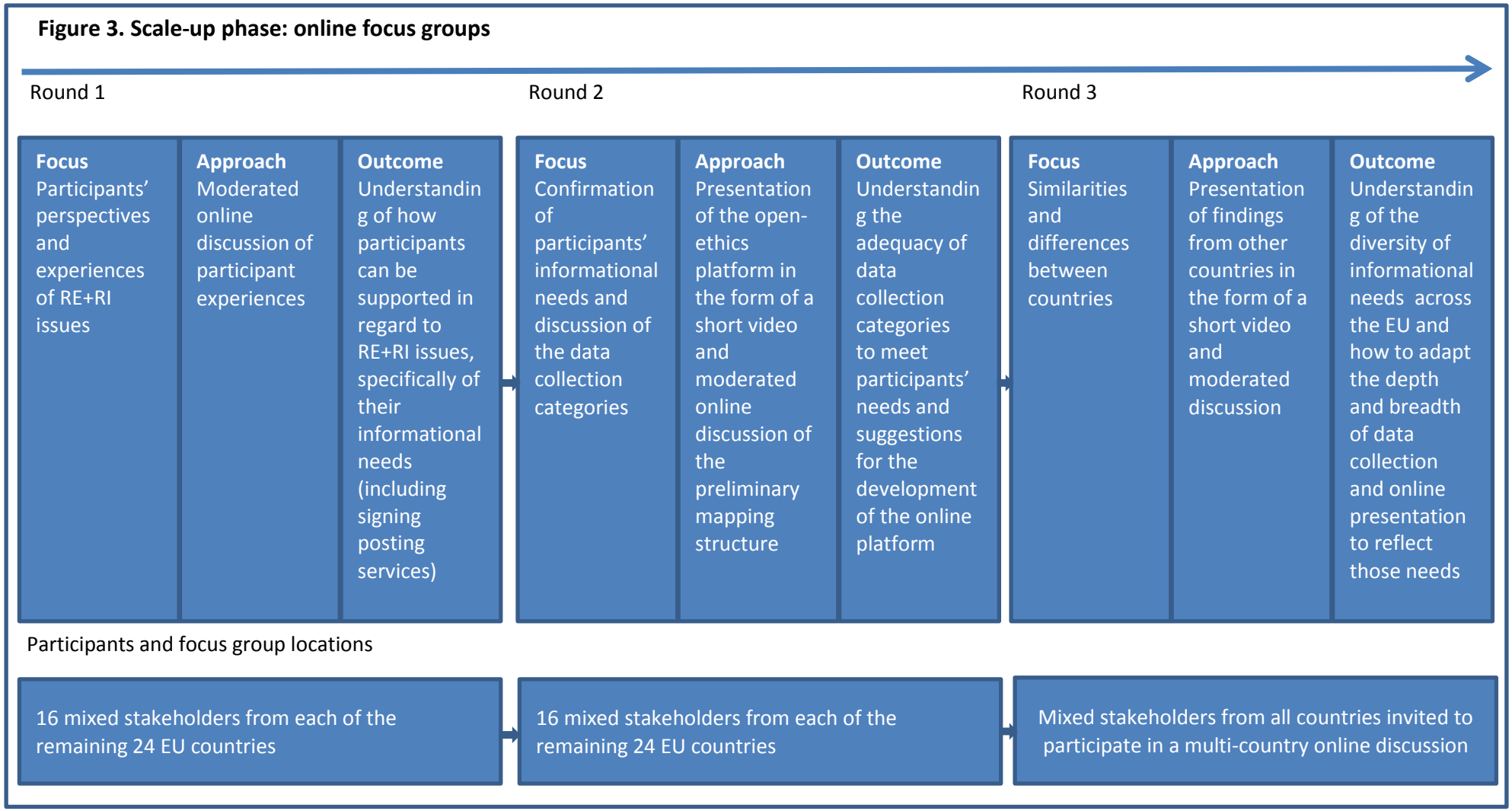


Figure 3. Scale-up phase: online focus groups



Participant benefits, burden and risk

Benefits

The direct benefits of participating in the research are that participants can share experiences and contribute to the development of the platform, thus being able to actively bring in and broaden their knowledge and experience; mostly, however, the benefits are indirect, they will be accrued by the research community as a whole which will benefit from access to a website that makes information about RE+RI easily accessible. The website will also potentially foster the uptake of ethical standards and responsible conduct of research in Europe, and ultimately support research excellence and strengthen society's confidence in research and its findings.

Burden

The burden of participation lies in the time commitment:

Face-to-face focus groups

- 1x questionnaire with background attributes (about 15 minutes)
- 2x 2.5hour focus group (and possibly a third, whole day workshop, if selected for the multi-country focus group)

Online focus groups discussions

- 1x questionnaire with background attributes (about 10 minutes)
- Multiple online interactions, the duration of which depends on the interest of the participant.

Risk

One risk associated with the focus group is the possibility of participants' personal knowledge of deviant cases being exposed to others or even made public. Efforts to mitigate this risk include asking all participants to return confidentiality agreements and to minimize the use of identifying characteristics. Participants will also be reminded to respect privacy and confidentiality at the beginning of each focus group (both face-to-face and online).

In addition, the time commitment required for two (and potentially three) focus groups discussions may prove inconvenient.

Ethics approval

Ethics approval has been applied for separately in the Netherlands, Spain and Croatia.

Data management

The burden of responsibility for data protection lies with the Dutch partner (VUmc). Any sensitive data collected will be stored electronically in 'Dark Storage', a maximum security data storage facility at VUmc. Audio recordings of face-to-face focus groups will be destroyed after they have been transcribed and quality checks have been conducted, and only the transcripts will be archived. These focus group transcripts will have identifying information removed as much as possible, and will only be accessible to authorized study personnel. Data from the online discussions will be collected through third party software. A suitable party will be chosen in the next months, and will be selected based on their compliance with EU data protection acts and their ability to guarantee anonymity. A data processing agreement with this party will be constructed and signed.

Analysis

The characteristics of the sample recruited will be described using descriptive statistics. Analysis of data generated during the face-to-face and online focus groups will be thematic. The preliminary data collection categories (guidelines, codes, legislations, and standards; committees, training courses and expert advice and contacts; and cases, casuistry and scenarios) will be used as a deductive coding scheme in initial line-by-line coding of the transcripts of the face to face focus groups and the text from the online discussions. Any topics that fall outside of this coding scheme will allow the coding scheme to be developed further and, subsequently, inform the both the focus group topic guide for subsequent discussions and data collection categories. Data analysis will be conducted using MAXQDA qualitative data analysis software.

Feedback to participants

In addition to the feedback provided to participants during and after the focus groups themselves, the findings from the stakeholder consultation will also be published and made publically available on the project's page on the European Commission research information portal:

http://cordis.europa.eu/project/rcn/210253_en.html

Stakeholder consultation and other EnTIRE work packages

There is close cooperation between the stakeholder consultation and other EnTIRE work packages.

Data collection (work packages 3-5)

There is a particularly close working relationship initially with the data gathering and synthesizing work packages 3-5. Like the stakeholder consultation these will progress in two phases – a pilot phase in the Netherlands, Spain, and Croatia, followed by a scale-up phase in all EU countries (Figure 4). The leads from the data collection work packages have been also been invited to attend the final multi-country workshop in order to have a clear overview of the similarities and differences between countries.

The outputs from the stakeholder consultation have been timed to arrive before the start of these work packages data collection, first in the pilot, then in the scale up phase. This is because the broad categories of information may need to be adjusted in order to deliver content that is appropriate for users' needs, as expressed during the consultation.

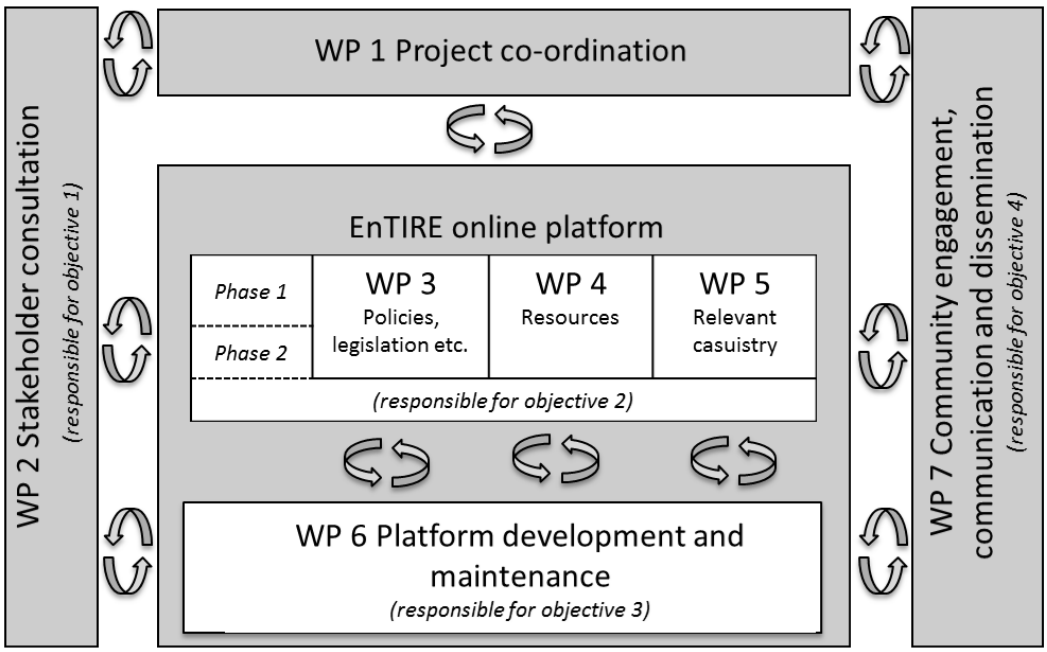


Figure 4. Description of work packages

Platform development and maintenance (work package 6)

The outcomes from the stakeholder consultation will influence the design and content of the online platform. The stakeholders involved in the consultation be asked to join the community of users of the platform who will add, edit and moderate content. Stakeholders will also be involved in the evaluation and improvement of the ease of use of the platform. The lead of the platform development and mainteance work package has also influenced the topic guide for the focus group's second round, which focuses more concretely on the online platform.

Community engagement, communication and dissemination (work package 7)

The community engagement work package will also invite the consultation participants, and their associated networks, to take part in engagement and dissemination activities.

Project co-ordination (work package 1)

The project coordination work package provides management and administrative support to the stakeholder consultation.

References

Crocker, J., & Cooper, M. L. (2011). Addressing scientific fraud. *Science (New York, NY)*, *334*(6060), 1182.

Nosek, B. A., Alter, G., Banks, G. C., Borsboom, D., Bowman, S. D., Breckler, S. J. et al. (2015). Scientific Standards: Promoting an open research culture. *Science*, *348*(6242), 1422-1425.

Rezabek R. Online focus groups; Electronic discussions for research. Forum Qual Soc Res 2000:1 [http://www.qualitativeresearch.net/fqs-texte/1-00/1-00rezabek-e.htm].

Schiek, D., & Ullrich, C. G. (2017). Using asynchronous written online communications for qualitative inquiries: a research note. *Qualitative Research*, 1-9. DOI:10.1177/1468794117690216.

Stewart, D. W., & Shamdasani, P. N. (1990) In *Focus groups: Theory and practice* (Vol. 20). Eds. Stewart, D. W., & Shamdasani, P. N. Sage publications, London

Woodyatt, C. R., Finneran, C. A., & Stephenson, R. (2016). In-person versus online focus group discussions: A comparative analysis of data quality. *Qualitative health research*, *26* (6), 741-749.

Appendix 1 - Stakeholder participation in EU RE+RI projects

Project	Overall aim	Aim of the stakeholder participation	Form of participation	Groups included
ENERI	ENERI is the GARRI 10 funded European Network of Research Ethics and Research Integrity. ENERI aims to bring together key players in RE+RI. I	ENERI facilitates the active exchange of experiences among the existing RE+RI networks and stakeholders through the development of a communication platform. Additionally, ENERI aims to produce up-to-date detailed comparison and benchmarking analysis of cases, good practice and models of excellence based partly on the results of stakeholder workshops.	Network activities; workshops; cross border hearings; and brokerage conferences.	REC, RIC, RE+RI networks, and stakeholders not directly involved in the project such as ministries, national funding agencies, universities and/or research institutions, journal editors, MEP, science journalists, and young researchers.
PRINTEGER	PRINTEGER is the GARRI 5 funded project 'Ethics in Research: Promoting Integrity'. It aims to improve governance of integrity and responsible research by improving the fit of governance to practice, improve integrity policies of national and international research organisations, and provide tools and resources for research leaders and managers.	Relevant PRINTEGER WPs include: WP 4 'Researchers' perspective', which aims to understand how researchers perceive, experience and address integrity issues, and WP 6 'Dissemination and communication', which includes a stakeholder consultation to raise awareness of the project, provide stakeholders with an opportunity to voice their priorities and to disseminate the project's findings.	The researchers' perspective is attained through a web-based e-survey and in-depth focus groups. The stakeholder consultation takes the form of small advisory stakeholder panels (described as 'scoping meetings') three times during the project period.	Future and early career researchers, research leaders and managers, policy makers, research support organisations, general public, media and opinion makers
SATORI	SATORI is an FP7 funded programme which aims to develop a common European framework for ethical assessment of research and innovation. It will develop a common framework of ethical principles and practical approaches to strengthen shared understanding among stakeholders involved in the design and implementation of research ethics.	Relevant SATORI WPs include: WP 2 'dialogue and participation', which aims to assess stakeholders training needs and their suggestions for participatory processes and capacity building activities, and WP 10 'communication', which is responsible for disseminating the project's findings and eliciting expert feedback.	Private and public stakeholders' perspectives and experiences are attained via a semi-structured interviews (n=230). The projects outcomes are disseminated, and expert feedback sought, during stakeholder workshops.	Stakeholder were categorized as research ethics assessors or non-research ethics assessors. Assessors include formal assessors (e.g. REC and RIC) and informal assessors (e.g. civil society organisations (CSOs), non-governmental organisations, science journalists, and special interest groups). Non-assessors include CSOs, governmental agencies/policymakers and media actors.

HEIRRI	HEIRRI is the H2020 research and innovation programme funded 'Higher Education Institutions and Responsible Research and Innovation' project. It aims to start the integration of Responsible Research and Innovation (RRI) within the formal and informal education of future scientists, engineers and other professionals involved in the research, design and innovation process.	HEIRRI incorporates on-line and off-line stakeholder participation in order to: raise awareness and knowledge of RRI; contribute to the co-development of Open Access specific instruments that stimulates the integration of RRI in professional careers; contribute to the integration and institutionalization of RRI debate within higher education institutions; and raise awareness of the activities of the HEIRRI project.	The on-line forum is conducted through social media (blog, twitter, facebook, YouTube, LinkedIn, and Researchgate). The off-line forum takes the form of two stakeholder conferences. Additionally, expert interviews (n=17) were conducted in order to identify RRI teaching resources.	Universities and Higher Education Institutions; Higher education accreditation organisations; Research Centres; Informal education institutions; Science editors; Policy makers; Professional and Civil Society organizations related to RRI; Organizations of entrepreneurship and social innovation; Secondary schools; Science Communicators; and Science Journalists
RRI-TOOLS	RRI-TOOLS is the FP7 funded Responsible Research and Innovation Toolkit project. It aims to develop tools for five key stakeholder groups to encourage and support them in taking up the concepts and practices associated with RRI.	RRI-TOOLS includes a WP dedicated to the compilation of stakeholders' needs and constraints. Its objectives include to: inform users about the RRI concept and engage them in its development; assess attitudes to RRI process and the developing toolkit; identify users' needs in regard to tools, relationships, training, and resources; identify constraints to participating in the RRI process; and engage and mobilise participants.	Stakeholder consultation workshops (27) across Europe with representatives from stakeholder groups, followed by a short e-questionnaire.	Policy makers; industry and business; civil society organisations; researchers; education
EnRRICH	EnRRICH is the H2020 research and innovation programme funded 'Enhancing Responsible Research and Innovation through Curricula in Higher Education' project. It aims to improve the capacity of students and staff in higher education to develop knowledge, skills and attitudes to support the embedding of RRI in curricula by responding to the research needs of society as expressed by CSOs.	Relevant EnRRICH WPs include: WP 2 'Identifying best practice, surveying needs and developing new course material in RRI' involves an initial consultation and analysis of needs in regard to RRI aspects in higher education. WP4 'Strengthening RRI in curricula through Science Shop work' aims to support incorporation of RRI in higher education curricula through Science Shops. WP 7 'dissemination' aims at engaging stakeholders in EnRRICH activities and on RRI curricula for use by HEIs. WP8 brings stakeholders together in a final conference.	Interviews with Lecturers and Directors of Education at Higher Education Institutes (n=31); Science shops; Social media (facebook, twitter, LinkedIn, Academia.edu); and a final conference.	Higher education staff (including lecturers and directors of education), research organisations, community partners, CSOs, policymakers, funders, students, the media, and other networks.

Appendix 2 - Participant information letter

Information in red must be adapted depending on the institution applying for the approval.

Invitation to participate in focus groups for the stakeholder consultation 'Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE)'

Dear Sir/Madam,

We at the EnTIRE project aim to create an online website that makes information about research ethics and research integrity easily accessible to the research community. This European Commission funded project seeks to include all stakeholders in a participatory way. As such, we are conducting an in-depth stakeholder consultation amongst people involved in research. We aim to consult: researchers, journal editors, national and local ethics/integrity committees, policy makers, representatives from industry (including pharmaceutical companies), and representatives from research funding organisations.

We would like to invite you to participate in these focus groups. By agreeing, you commit to participating in two separate discussions approximately one week apart in (insert city). They will be led by researchers from VU University Medical Center (in collaboration with The University of Split Medical School/European University of Madrid). As this is a Europe-wide consultation, the language of the focus groups will be English. Furthermore, one third of participants from the Dutch/Spanish/Croatian focus groups will be invited to participate in an additional focus group in Amsterdam that will bring together participants from parallel studies in (insert the two other countries) to discuss similarities and differences between countries.

All focus group discussions will take place in Autumn 2017. This letter contains details about the project and the stakeholder consultation so you can make an informed decision whether you would like to participate in the focus groups or not.

1. Aim of the focus groups

In the first focus group, we will discuss your experiences of research ethics and research integrity issues. This will allow us to develop an understanding of any difficulties you might encounter as well as ideas you might have on how you could be better supported in the future, particularly in regard to informational needs. For example, if researchers say they do not know data management guidelines, or the procedure for raising concerns about integrity of research practices, or, alternatively, have suggestions for improvement, we can identify those issues and suggestions as relevant for gathering information and putting this on the website.

The second focus group, taking place approximately two weeks later, will involve a presentation of the pilot version of the website and a discussion about its content and presentation. This will further help us understand if we need to collect any information additional to the preliminary data collection categories of: guidelines, codes, legislations, and standards; committees, training courses and expert advice and contacts; cases, casuistry and scenarios. Participants will also help us understand if we are presenting information in an optimal way or how this might be improved.

The third, potential, focus group, will bring participants together from the Netherlands Spain, and Croatian to discuss similarities and differences between countries. This will provide us with an understanding of the diversity of informational needs across different EU countries, and with suggestions on how to deal with them in presenting data on the website.

2. What is involved?

If you would like to participate, we will invite you to two focus group sessions at the VUmc, Amsterdam. The preliminary dates are:

Round 1. date of first focus group

Round 2. date of second focus group

Each of these focus groups will take about 2 hours.

There is also the possibility that you will be invited to a day-long workshop held at the VUmc, Amsterdam, that will bring together one third of the participants from the focus groups in the Netherlands, Spain, and Croatia.

Round 3. date of third focus group

If you cannot make these dates but would like to join the focus groups, we would still like to hear from you as we might conduct individual interviews with stakeholder groups under-represented in the focus group discussions.

Before attending the focus group, we will ask you to complete a short questionnaire (sent via email and taking about 15 minutes) about your background: gender, age, role (depending on the stakeholder group – e.g. academics will be asked their area of expertise (biomedical, social sciences, natural sciences, applied sciences) and position (PhD student, Research Associate, Assistant Professor, Professor, Head of Department), years of experience, nationality and country of residence. The questionnaire will also include a couple of open questions about what you know about research ethics and research integrity and what support is currently available to you.

3. Benefits and risks of participating

The direct benefits of participating in the research are that participants can share experiences and contribute to the development of the platform, thus being able to actively bring in and broaden their knowledge and experience; mostly, however, the benefits are indirect, they will be accrued by the research community as a whole which will benefit from access to a website that makes information about research ethics and research integrity easily accessible. The website will also potentially foster the uptake of ethical standards and responsible conduct of research in Europe, and ultimately support research excellence and strengthen society's confidence in research and its findings. One risk associated with the focus group is other people knowing the details about any research misconduct you might describe. Efforts to minimize this risk include asking all participants to return confidentiality agreements, and to avoid the use of identifying characteristics. In addition, the time commitment required for two (and potentially three) focus groups discussions may prove inconvenient.

4. If you do not want to join or want to stop the group conversation

Participation is voluntary. If you do not want to participate, you do not have to do anything and you are not required to let us know. If you decide to participate, you must sign the attached informed consent form and return it via email prior to the focus group. If you have agreed to participate but change your mind, you can of course withdraw at any point (including during the focus group discussions), we would ask you kindly to inform us if this is the case.

5. Use of data and dissemination of research findings to participants

The focus groups will be recorded. These recordings will be destroyed after they have been transcribed. The transcripts of the focus groups will be kept for up to 15 years after the end of the study (in accordance with EU and Dutch/Spanish/Croatian data protection laws). All data is anonymised for analysis. The findings from the stakeholder consultation will also be published and made publically available on the Project's page on the European Commission research information portal:

http://cordis.europa.eu/project/rcn/210253_en.html

6. Financial aspects

There is no fee paid for participation, however all travel expenses will be reimbursed. If you are invited to the third, international focus group, your travel and accommodation will be reimbursed according to local university rules and you will receive 70 euros per diem to cover your expenses in the country.

7. Do you have any questions?

Please do not hesitate to contact the consultation project coordinator, Dr. Natalie Evans n.evans@vumc.nl, if you have any hestions.

Appendix 3 - Participant questionnaire

Basic background variables - all stakeholder categories

1. What is your country of residence?

2. What is your nationality?

3. What is your gender?
Mark only one oval.

- Female
- Male
- Prefer not to say
- Other: _____

4. What is your age? _____

5. How well do you speak English?
Mark only one oval.

	1	2	3	4	5	
I don't speak English very well						I speak English very well

6. **Are you currently active in some stage of the research process (e.g. research, publishing, policy, research funding?**

   Mark only one oval.

   - ⬭ **Yes**
   - ⬭ **No**

7. **If you answered 'yes' to the previous question, please indicate in which role:**
   Check all that apply.

   - ☐ **As a researcher**
   - ☐ **As a journal editor or assistant editor**
   - ☐ **As a member of a research ethics or research integrity committee**
   - ☐ **As a policy maker**
   - ☐ **As a research policy, training and compliance officer in industry**
   - ☐ **As working for a research funding organisation**
   - ☐ **Other:** _____

8. **How many years have you been active in this role?**

   _____

Background - Researchers

1. **In which discipline(s) do you work?**
   Check all that apply

   - [ ] **Biomedical sciences**
   - [ ] **Social sciences**
   - [ ] **Natural sciences**
   - [ ] **Applied sciences**
   - [ ] **Other:** _____

2. **At which professional level(s) do you work?**
   Check all that apply.

   - [ ] **PhD Student**
   - [ ] **Research Associate**
   - [ ] **Assistant Professor**
   - [ ] **Associate Professor**
   - [ ] **Professor**
   - [ ] **Head of Department**
   - [ ] **Other:** _____

3. **In which sector(s) do you work?**
   Check all that apply.

   - [ ] **Academia**
   - [ ] **Industry**
   - [ ] **Other:** _____

4. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

   _____

   _____

   _____

   _____

   _____

5. **Please briefly describe your experience with research ethics and/or research integrity issues:**

6. **Please briefly describe your interpretation of the term 'research integrity':**

7. **Please briefly describe what kind of support for fostering research integrity is currently available to you:**

8. **Please indicate what kind of support for fostering research integrity you find lacking in your current position:**

Background - Journal editors and assistant editors

1. **Which discipline(s) does your journal cover?**
   Check all that apply.

   - [ ] **Biomedical sciences**
   - [ ] **Social sciences**
   - [ ] **Natural sciences**
   - [ ] **Applied sciences**
   - [ ] **Other:** _____

2. **In which editor role(s) do you work?**
   Mark only one oval.

   - ◯ **Editor**
   - ◯ **Assistant editor**
   - ◯ **Other:** _____

3. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

   _____
   _____
   _____
   _____
   _____

4. **Please briefly describe your experience with research ethics and/or research integrity issues:**

   _____
   _____
   _____
   _____
   _____

5. **Please briefly describe your interpretation of the term 'research integrity':**

6. **Please briefly describe what kind of support for fostering research integrity is currently available to you:**

7. **Please indicate what kind of support for fostering research integrity you find lacking in your current position:**

Background - Members of RE+RI committees

1. **At which geographical level(s) does your committee work?**
   Check all that apply.

   - [ ] **At national level**
   - [ ] **At local level**
   - [ ] **At institutional level**
   - [ ] **Other:** _____

2. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

3. **Please briefly describe your experience with research ethics and/or research integrity issues:**

4. **Please briefly describe your interpretation of the term 'research integrity'**

5. **Please briefly describe what kind of support for fostering research integrity is currently available to you:**

6. **Please indicate what kind of support for fostering research integrity you find lacking in your current position:**

Background - Policy makers

1. **On which geographical scope are you involved in policy making?**
   Check all that apply.

   - [ ] **On a national scope**
   - [ ] **On a regional scope**
   - [ ] **On an institutional scope**
   - [ ] **Other:** _____

2. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

3. **Please briefly describe your experience with research ethics and/or research integrity issues:**

4. **Please briefly describe your interpretation of the term 'research integrity':**

5. **Please briefly describe what kind of support for fostering research integrity is currently available to you:**

6. **Please indicate what kind of support for fostering research integrity you find lacking in your current position:**

Background - Research policy, training and compliance officers from research intensive industries

1. **In which research intensive industry or industries do you work?**
   Check all that apply.

   - [ ] **Engineering**
   - [ ] **Biotechnology**
   - [ ] **Nanotechnology**
   - [ ] **Pharmaceutical**
   - [ ] **Chemical and Materials science**
   - [ ] **Electronics**
   - [ ] **Aerospace**
   - [ ] **Automotive**
   - [ ] **Other:** _____

2. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

3. **Please briefly describe your experience with research ethics and/or research integrity issues:**

4. **Please briefly describe your interpretation of the term 'research integrity':**

,

5. Please briefly describe what kind of support for fostering research integrity is currently available to you:

6. Please indicate what kind of support for fostering research integrity you find lacking in your current position:

Background - Research funding organisations

1. **On which geographical scope is your organisation involved in funding research? Check all that apply.**

   - ☐ **On a national scope**
   - ☐ **On a European scope**
   - ☐ **Other:** _____

2. **In which domain(s) does your organisation fund research? Check all that apply.**

   - ☐ **Biomedical sciences**
   - ☐ **Social sciences**
   - ☐ **Natural sciences**
   - ☐ **Applied sciences**
   - ☐ **Other:** _____

3. **Please briefly describe what your interest in research ethics and/or research integrity issues entails:**

   _____

   _____

   _____

   _____

   _____

4. **Please briefly describe your experience with research ethics and/or research integrity issues:**

   _____

   _____

   _____

   _____

   _____

5. **Please briefly describe your interpretation of the term 'research integrity':**

6. **Please briefly describe what kind of support for fostering research integrity is currently available to you:**

7. **Please indicate what kind of support for fostering research integrity you find lacking in your current position:**

Appendix 4 - Informed consent and confidentiality agreements

Informed consent and confidentiality agreement

Please read the statements below in connection with the research **'**Mapping the Normative Framework of Ethics and Integrity of Research (EnTIRE): stakeholder consultation' and sign if you are in agreement with all of the statements.

- I have read the information sheet.
- I was given the opportunity to ask any questions and any questions I did have were sufficiently answered.
- I had enough time to decide if I would join.
- I know that participation is voluntary. I also know that I can decide at any time that I would like to withdraw my participation and quit the study. I do not have to give any explanations.
- I give permission to make the sound recording.
- I give permission for collecting and using my data in the way and for the purposes stated in the information letter.
- I want to participate in this research.

- **I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session.**

Name:

Signature: Date: __ / __ / __

Appendix 5 - Focus group topic guides

Introduction — 15 min

Introductory round
Presentation of the project and plan of consultation

Focus group round 1

What is RI/Good research practice?

Support

What do you know about RI?
What does good research practice or RI mean to you?
Where have you heard it from?
In which contexts has it been discussed?
Tell me about the kinds of support for RI/good research practice that exist in your work place?
Can you tell me about the approach to RI in:

- Guidelines
- Training
- Role models

Do you think RI is approached differently in different disciplines/sectors?

Needs

What are your support needs?
What kinds of support currently sufficient/insufficient?
Are the current support measures appropriate to your discipline/sector?
Can you find it?

- How should support be offered?
- How can we support you through the online platform?

Experiences — 2 hrs

Country specific example provided to provoke discussion

- Tell me about a time when you witnessed research that did not meet what you consider good research practice?
- Why was that?
- How could that situation have been avoided/the researcher supported?

Policy

How much emphasis is put on research integrity in:

- Institutional policy
- Departmental policy
- Government policy
- Ethics approval
- Funding criteria
- Research intensive industries

Categorization of emergent topics and themes — 15 min

Introduction of the preliminary data collection categories
Categorization of the topics discussed into the preliminary data categories- is it possible for all of them? Anything additional needed? Do you have good examples for the categories/cases from your experience?

Focus group round 2

Feedback — 15 min

- Feedback to participants about the themes identified from the first focus group
  - How do these themes reflect or not reflect the discussion we had last week?
  - Is there anything you would change/add?

Website introduction — 15 min

- Presentation about the website and the preliminary collection categories
- Participants navigate the website on iPads (in pairs)

What do you think about the platform?

Design

- What do you think about the platform?
- Would it attract people from your discipline/sector?
- What did you think about design of the:
  - the logo
  - the home page
  - the search feature
- Do you have anything else you want to say about the website design?

Usability

- What do you think about the platform's usability?
- Is there anything you would change? How would you change it?
- What do you think about the navigation?
- Are the information upload, edit and moderation features easy to use?

Structure — 2 hrs

- What do you think of the website's planned structure (data collection categories)?
- Is there anything else you would like included?
- Are the preliminary data collection categories adequate to meet the needs identified from the first focus group? Is something lacking?

Content

- What do you think about the content to be gathered under the data collection categories?
- How is it sufficient or insufficient to meet your needs?
- Is there anything else you would like included?
- Do you have any further content suggestions?

Introduction and feedback — 20 min

Focus group round 3 – morning of full day workshop

- Introductory round
- Feedback to participants about the themes identified from the first focus group round in Croatia, the Netherlands and Spain and a comparison between the three countries

2.5 hrs

Needs and support

- Where do countries have similarities and differences in:
  - knowledge and understanding of RI and good research practice?
  - the support available?
- What do you think about the similarities and differences in support needs -
  - By country?
  - By discipline/sector?
- How do you think these differences and similarities in needs and available support should be reflected in the online platform?

Similarities and differences

Experiences

What do you think about the similarities and differences between countries in experiences regarding research behaviours?

How do these similarities and differences help you better understand (in your country and elsewhere):

- The content of research (mis)conduct
- The drivers of research (mis)conduct
- The diversity of norms governing science
- Ways to address research (mis)conduct

Policy

What do you think about the similarities and differences between countries in:

- Institutional policy
- Departmental policy
- Government policy
- Ethics approval
- Funding criteria
- Research intensive industries
- How RI is approached in different disciplines/sectors

How do you think these differences and similarities should be reflected in the online platform?

Focus group round 3 – afternoon of full day workshop

Feedback — 20 min

- Feedback to participants about the themes identified from the second focus group round in Croatia, the Netherlands and Spain and a comparison between the three countries

2.5 hrs

Design

- What do you think about the similarities and differences between countries attitudes towards the website design?
- How can we make the platform attractive to people from all EU countries, disciplines and sectors?

Usability

- What do you think about the similarities and differences between countries in attitudes towards the platform usability?
- How can we make the platform intuitive and usable for people from all EU countries, disciplines and sectors?

How can we reflect the similarities and differences between countries in the online platform?

Structure

- What do you think about the similarities and differences between countries in attitudes towards the platform structure (data collection categories)?
- How can we make the structure relevant for all EU countries, disciplines and sectors?

Content

- What do you think about the similarities and differences between countries in informational needs?
- How can we best support different informational needs on the platform?
- Is there anything else you would like included?
- Do you have any further suggestions?

Evaluation and close — 5 min

Participants thanked and informed that they will be sent a short evaluation form by email