PRO-RES

PROmoting integrity in the use of **RES**earch results in evidence-based policy: a focus on non-medical research

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1 Introduction

This deliverable **synthesizes the outcome**s from the interactions between the PRO-RES project and various agencies, policy makers and science advisors that were undertaken under WP4/2/3. Interactions with SRA, AZOP, UKRIO, the Estonian Research Council and national research councils and other governmental organizations with influence on research governance and conduct are included. The **aim of the report is to detail the nature of the interaction** for each stakeholder category, **capture all the feedback** that PRO-RES received from them and i**nclude any recommendations and/or lessons learned** from the interaction that could be reflected in the development of the PRO-RES Framework.

2 Description of the interaction with project PRO-RES

2.1 INGSA

The European Alliance for Social Sciences and Humanities (EASSH) organised a series of 'dialogues' with the International Network of Governmental Science Advice (INGSA). The senior representatives who took part int the dialogue all asked to remain unnamed as they expressed their own views on how INGSA is considering research ethics and integrity issues from within the network.

The mission of INGSA is to provide a forum for policy makers, practitioners, national academies, and academics to share experience, build capacity and develop theoretical and practical approaches to the use of scientific evidence in informing policy at all levels of government. Its primary focus is on the place of science in public policy formation rather than advice on the structure and governance of public science and innovation systems.

The dialogues included:

1) Interviews with members of the International Network Governmental Science Advisors from different countries; and

2) feedback and documents from INGSA courses to assess if science advisors receive any training on research ethics and integrity.

The specific structure of each dialogue was adapted to the interviewees' backgrounds. The aim of the dialogues was to collect the science advisors' understanding and insights about research and how they establish that the feedback they communicate originates from methodologically robust and ethically grounded research. This presented:

a) A unique opportunity to assess the understanding of science advisors about how different types of research (beyond biomedical research) could have ethical implications and to see how across different countries they perceive the risk of research, which is not ethically tested or methodologically robust;

b) The opportunity also to discuss with science advisors the details of the PRO-RES ethical framework and interactive platform on people who directly or indirectly are involved in assessing if their research has been implementing the values and principles of the ethical framework.

The duration of each dialogue was approximately 30–90 minutes, the dialogues were not formally recorded to accord with the wishes of the participants. All notes collected in the dialogue remain with the interviewers as per participants' wishes. Interviews were conducted in English, and the interviews will not be reported in the publicly disseminated reports for the Project.

2.2 UKRIO/ARMA

This case study involved an on-going project sponsored by the United Kingdom Research Integrity Office (UKRIO) and the Association of Research Managers and Administrators (ARMA (UK)). UKRIO is an independent charity, in the sense that it is not affiliated with any specific institution. Funded by subscriptions from UK research organizations, it might be thought of as a 'producer co-operative', offering support to the public, researchers and organisations to further good practice in academic, scientific and medical research. ARMA (UK) is the professional association for research management in the UK. The aim of the project was to provide a common framework for ethics review and ethics support for universities and other research organisations, paralleling the Governance Arrangements for Research Ethics Committees (GAFREC) of the UK National Health Service Health Research Authority, which is the national level framework for ethics review of medical and health research.

The background to the project dates back to 2013, when a working group of the UK Association for Research Ethics (AREC) produced a 'Framework of Policies and Procedures for University Research Ethics Committees'. This aimed to 'encourage continued reflection, evaluation and development towards a set of common best practice standards. [and] a means of evidencing the ways in which these standards are demonstrated in the specific practices of individual (Higher Education Institutions) HEIs'. The guidance in the document was based on extensive liaison and consultation across the university sector and was widely welcomed. It was intended to be 'an initial, rather than a final, statement … intended to stimulate reflection and in this spirit expected to require review and revision as a result of its use'.

Since its publication, general concern increased regarding the importance of best practice in the support of ethical research conduct. A need was perceived for a more formal framework taking account of developments in the research ethics and integrity landscape since the AREC work. The need was articulated as for providing detailed procedural recommendations for a broader approach, seeing ethics committee review as one part of a broader institutional commitment to ensuring end-to-end support of ethical practice through all phases of research processes.

UK ethics review and support processes in different universities and other research organisations vary widely in their modes of operation and there is a diversity of approaches. This is highlighted when collaborative research involving more than one institution takes place, and in cases where ethics review 'falls through the cracks' or is treated only cursorily by researchers. There is a common view among researchers that ethics review is a barrier to progress and it is often seen as a hurdle to be overcome rather than a facilitative aid to ensuring high standards. For many institutions, the single, pre-emptive ethics review is narrowly seen as the only necessary action to monitor research ethics standards.

The UKRIO/ARMA framework seeks to address these concerns and provide a means for research institutions to achieve harmonised best practice across the sector.

The strategy adopted to aim to achieve this was to involve authors in the core team who had also worked with other stakeholders, including funding bodies, government departments and learned societies in developing research ethics guidance and to establish an active advisory group representing key stakeholders. This ensured that the framework was consistent with the expectations of bodies such as the Economic and Social Research Council, Universities UK, the British Psychological Society and the Academy of Social Sciences, and beyond the UK, the European Research Council, for competent ethics review.

2.3 The SRA

The Social Research Association (SRA) study concerned the history of an update that was needed to help the SRA, UK and Ireland's professional membership body for all who practice, use, or have an interest in social research, and its members (from academia, government, the third sector, commercial research firms of all sizes, and those who work as independent researchers, as well as retired researchers, student researchers, and others) maintain their professional standards.

The SRA saw it as part of its remit to provide guidance on research ethics, in particular to researchers who didn't have a lot of support to think through ethical issues and dilemmas. The first iteration of the Ethical Guidelines was published in 1983, then in 2003 the SRA published its revised Ethical Guidelines. These proved very popular with the SRA's members and the wider research community. By 2012 it was decided that the Guidelines should again be updated. For example the 2003 Guidelines made no reference to research using social media which had become increasingly popular by 2012.

2.4 Estonian Code of Conduct

This case study focused on the process leading to signing of the Estonian Code of Conduct for Research Integrity in 2017. The motivations behind creating the code included the need to achieve common understanding on matters related to research integrity as well as educational and awareness-raising, preventive and regulatory aims, the need for broader quorum and common understanding and the fact that other countries have their code. The process of compiling the code of conduct lasted a couple of years and the description of it opens the possibilities to analyse positive and negative experiences during the compiling of document of research ethics, the course of consensus making and feedback to the document.

The local case study allows on one hand a unique description that would be comparable with the experiences of other European countries and, on the other hand, the possibility to "test" the idea of a general ethical framework on people who directly or indirectly were involved in either formulating the code of conduct or implementing the values and principles underlying it.

For capturing the case study a document analysis and some semi-structured interviews were carried out between November 2019 and April 2020, with four research questions:

- What were the motivations behind creating the code? (Document analysis, Interviews)
- How was the code created? (Document analysis, interviews)
- Who and by what means were included in the development of the code? (Document analysis, interviews)
- What do different partners think about the final version of the code? (Interviews)

2.5 AZOP

Another case study was conducted in cooperation with the Croatian Agency for Personal Data Protection (AZOP), aiming to explore how scientific and research institutions in the Republic of Croatia recognize the importance of data protection and privacy and how the implementation of GDPR impact the field of research and integrity (R&I). The first part of the study was based on the personal data protection requests that the national authority in Croatia had received before and after GDPR, and how many of those were related to research. In Croatia, the relevant agencies are learning how to work together and with the research institutions, at the same time as introducing new legislation/regulations. Review practices are in their early stages and the opportunity for avoiding the 'errors' of previous and existing systems in other countries could be exploited. The main partner for this Case study was the Croatian Agency for Data Protection (Agencija za zaštitu osobnih podataka - AZOP).

The study involved:

a) Qualitative analysis of all reported cases compared to those coming from the scientific and academic institutions allowing to detect the current situation in the R&I field.

b) Due to the COVID-19 crisis, instead of conducting face-to-face interviews with members of Research Ethics Review Boards, a cross-sectional study on 732 data protection officers in Croatia was conducted via an online survey.

c) Comparison of the procedures and practices from other EU data protection agencies with AZOP procedures. Some EU data protection agencies do not provide specific answers to parties which contact them, but act more like a "general controller" of data protection without providing an advisory role to the broad public community as the AZOP currently does.

d) A further research step which enabled an exploration of how the pandemic influenced the field of personal data protection based on the reported cases to AZOP related to pandemic. However, this research was later terminated from the side of the agency.

e) Previously unplanned access from the European Commission's Research Executive Agency (REA) to conduct a study related to detected ethics issues on all received H2020 proposals during the entire framework period (2014-2020), exploring the ethics appraisal procedures that had been conducted on H2020 proposals.

f) RESEARCH BEYONG PROJECT TIMELINE, since we already prepared all protocols for face-tp-face interviews and since we already established contacts with large numbers of Ethics Boards in Croatia, as soon as the COVID-19 epidemical situation will allow, we will contact the initially planned face-to-face interviews. These results will allow us to clearly determine the previously identified lack of communications between DPOs and Ethics Boards

3 Listing the feedback to PRO-RES

3.1 INGSA:

In the process of preparing their Manifesto 2030 (which is a work in progress) a senior representative of INGSA said that the document emerged from discussions at their bi-annual conferences (Brussels and Tokyo) led by some senior members of the network, with broad consultations and without a formal process in line with the informality of the organisation itself.

The next conference will be in Canada, in September 2020 and PRO-RES has been invited to submit a proposal for a session. In fact, although it is recognised that having a code of ethics for non-medical fields is recognised as important, it has never been one of the objectives of the manifesto. Yet it was acknowledged as a tool for senior members of the network to sensitize INGSA 'loose memberships'.

A fundamental element of their feedback was that most of their interests in the discussion about science advice focus on how to identify good evidence and what does actually constitute good evidence. Consideration of reputed science publications, high reputation scholars and institutions and reliable sources providing robust and reproducible results are crucial for identifying good evidence.

However, research ethics especially for non-biomedical sciences (including engineering, politics and finance for example) is difficult to identify. Furthermore, the integrity of scholars in presenting their results is usually guaranteed by the host institution or the reputation itself of the scholar. Whereas there seems to be a number of mechanisms to look into research results assessments, there seems to

be little concern and therefore no scrutiny to assess if the evidence is ethically sound. Particularly, in certain research areas such assessment is beyond the capacity of the advisors' capacity to engage.

Therefore, the Manifesto is mainly based on the capacity of advisors to bridge between the scientific output and its most complex publications and the narrative of policy making and policy focus of interest. This exercise already presents numerous difficult steps and the robustness of the research or the ethical approach to research topics remains assumed as it is mainly related to the primary aim to produce research results.

This should not be surprising given that we are aware that the ethics of research and the integrity of scholars are still considered to be in the realm of scholars' training. However, from the interviews it emerged that INGSA does not engage its members with conversations about the effects of drawing from research results which are not ethically sound. Paradoxically, the role of integrity in research, reproducibility of experiments and validation of results are embedded in the search for 'good evidence', whereas research which has not followed ethical protocols is not even highlighted as a source of misinterpretation and even misleading results.

3.2 UKRIO

How the guidance was seen to be likely to be promoted and used:

It was planned for the guidance to be disseminated through the networks of the two sponsoring bodies, with the launch to coincide with the publication by Universities UK of the revised Concordat on Research Integrity. The development work on the framework has sought to achieve compliance with the expectations of the Concordat.

The summary and full documents are held on the websites of the two sponsoring bodies, and these bodies promote and support the use of the framework. In the year following the launch, the framework has been used extensively by universities reviewing and modifying their review processes and by charities and other research organisations establishing review processes de novo.

3.3 SRA

Initially the SRA's Board of Trustees assigned responsibility for the revisions to the Board member leading on ethics. That person made a revision in early 2015 but it was judged by the Board to be unfit for purpose. At the same time the Academy of Social Sciences (AcSS) published their five ethical principles which had been collaboratively developed as suitable for the range of disciplines constituting the Academy's membership. The UK's Government Social Research department (GSR) had also produced six ethical principles. The SRA decided to use these two sets of principles as a basis for revising their own Guidelines.

In late 2016 the SRA called for volunteers from among its membership to help revise the Guidelines. A number of people volunteered, eight of whom went on to work on the Guidelines alongside the then Chair of the Board of Trustees and with organisational assistance from the Chief Executive. The volunteers were from different geographical areas and in different forms of employment: academic researchers, government researchers, researchers in the charity sector and independent researchers. There were five face-to-face two-hour meetings over 18 months from January 2017. The group agreed at the start to continue with the principle from the Guidelines of having advisory guidelines to help researchers think through issues rather than a code of conduct to tell people what to do.

Initially the AcSS and GSR principles were used as headings for six chapters. Group members were paired up to draft chapters in between meetings. Chapters in draft were shared with all group members before meetings, and meetings were used to discuss content. The theoretical basis was

virtue ethics. After a couple of meetings, a decision was taken to collapse the six chapters into four, as the group felt this could be done without losing value. Then the group started the drafting process again and went through three more meetings before they felt they had gone as far as they could with so many people involved.

At this point some chapters were much longer than others and the document as a whole included a range of writing styles. So they decided to take the document forward with a smaller group of three people to work on editing it for consistency. That was again done through face-to-face meetings interspersed with work on drafts. By early 2019 it was deemed ready to go to a research ethics expert for feedback. Three trustees also took a close look at the guidance, and they and the expert made many useful observations and criticisms. The Chief Executive of the SRA and the former Chair of Trustees, now a volunteer on the project, needed to consult experts on some specific points raised by trustees, which took time, and then the COVID-19 pandemic caused further delays.

How the guidance is likely to be promoted and used:

The new guidelines have been launched and can be found in the SRA website[1]. Guidelines were promoted on the SRA's website, in its newsletter, on its blog, through social media, and via correspondence with other organisations and contacts. The was promoted through training courses and events offered by the SRA. Members of the working group also promoted the guidelines.

The guidance is most likely to be used by social researchers who need help with a specific ethical difficulty and don't have access to useful institutional resources. Those who worked on the guidance hope it will help researchers in complex situations to make good judgements. The guidance may also be used by novice researchers as a comprehensive resource to help them start thinking systematically about ethics, and by academic researchers at any level as a toolkit for reference. Also, it can be pointed to as an authoritative source by researchers working with others who may not have a solid understanding of research ethics, such as commissioners of research.

At present there is a link to PRO-RES from the 'research ethics guidance' page of the SRA website, and a link to the SRA from the PRO-RES website. It remains to be seen how the revised guidance will be received by the target audiences. Also the SRA doesn't yet have a plan for maintaining their new guidance in the future, though their intention is to review the guidance every five years.

3.4 AZOP

During the implementation of WP4.3, PRO-RES achieved strong and fruitful cooperation with AZOP. The topic explored, protection of personal data in science and research, becomes each day more and more important with the introduction of new and emerging technologies (e.g. AI, CRISPR etc.). Our partner AZOP have expressed willingness to use the information arising out of this PRO-RES National Case study (WP4.3) results in their future presentations, educations and workshops, which are regularly organized for data protection officers. Furthermore, with this work, we clearly demonstrated some deficiencies of the current GDPR shape and the need for its further future improvement, primarily when implemented in scientific research, academia and R&I in general. These deficiencies are even more important for EU countries like Croatia, which failed to include derogations of GDPR for scientific purposes on a national level. The importance of this topic is clearly recognized not only from AZOP then also from the European Data Protection Board (EDPB). That is why the EDPB recently organized the Stakeholder Event on the processing of personal data for scientific research purposes on the 30th of April 2021. Furthermore, our results showed some different perceptions in the

[1] https://www.the-sra.org.uk/SRA/Ethics/Research-ethics-guidance/SRA/Ethics/Research-Ethics-Guidance.aspx?hkey=5e809828-fb49-42be-a17e-c95d6cc72da1

understanding of ethics requirements between scientists (grant applicants) and ethics experts who evaluated applied proposals. These differences are highly visible in questions related to personal data protection and therefore pointing on one side to the need for continuous applicant education in ethics and from the other side to the need for additional explanations of application rules related to ethics assessment procedures.

It is planned that the research will continue beyond the project lifetime. As soon as the COVID-19 epidemiological situation allows, the PRO-RES project partner CUC, will try to conduct the initially planned face-to-face interviews with members of different Ethics Review Boards across the Republic of Croatia.

3.5 ESTONIAN CODE OF CONDUCT

The process of developing and signing the Estonian Code lasted for a year and a half. Estonian Research Council (ETAg[2]) invited different universities and research organisations to participate in the working group behind the code. Overall, 11 meetings were held during the period of 20 months (from March 2016 to October 2017) with additional work done between the meetings on different documents (e.g. Danish code, Singapore, ALLEA etc., and internal guidelines from participating universities) and drafting the key points for the code.

Two consulting rounds were held, one for the public during the process and one with the partners from research and development institutions. Overall, 23 institutions signed the code: 21 nationally accredited research institutions, ETAg and the Republic of Estonia Ministry of Education and Research[3].

Division of roles and cooperation

Before the official writing of the Estonian Code of Conduct for Research Integrity started, there were two initiatives formed: the working group of ETAg and the working group of Centre for Ethics of University of Tartu. The ETAg working group consisted of representatives of universities, appointed by the rectors, a representative from the Estonian Academy of Sciences, a representative from the ministry of education and research and members of the ETAg. The working group of the Centre for Ethics consisted of the University of Tartu employees who were tasked by the rectorate of the university with creating a code of conduct for research integrity for the university.

The final working group was created by joining two initiatives: the initiative of the ETAg to create a new national framework for research integrity and the initiative of the University of Tartu to create a code of conduct for research. According to the interview with the representative of the ETAg, the idea of a new code for research was influenced by their previous research integrity related work with the ENRIO and Science Europe and ETAg thus started and coordinated this process. By turning to the Universities Estonia, an association of rectors of Estonian public universities, the University of Tartu was invited to participate in the process. The ETAg sent a separate invitation to the Centre for Ethics, which they considered competent in this field. What was exceptional in the eyes of ETAg about the

[2] The abbreviation for Estonian Research Council in English should be ERC, however, since the abbreviation "ERC" is more commonly known as European Research Council, the Estonian abbreviation ETAg (*Eesti Teadusagentuur*) is used in this document.

[3] In February 2019 Archimedes Foundation, the national agency of the European Union's education, youth and sports program Erasmus+ and the European Solidarity Corps in Estonia (https://archimedes.ee/en/archimedes-foundation/), also requested to sign the code, making it 24th organisation to join, https://www.eetika.ee/et/uudised/sa-archimedes-uhines-hea-teadustava-kokkuleppega.

formed working group was the fact that everything was organised informally. No directive was given out to form the working group, all the partners attended based on common interest and consensus.

Once the working group had finished working on the Code, it was opened for a public round of feedback. The call was sent to all the Estonian research institutions and universities and was open for one month. Overall, 108 comments were made by 17 people. From the comments made, 56 were included or included partially in the text, 20 were acknowledged and 31 were rejected.

As both ETAg and CEUT were collecting feedback, it was later perceived as dishonest when ETAg simply forwarded feedback to CEUT for further analysis. Instead, the addressee should have been the CEUT to begin with.

All in all, most of the resistance and critique towards the new Code was never directly addressed towards the working group. Because these discussions and critique took place outside of the established feedback channels, mainly internal mailing-lists and personal letters to the ETAg members, and were therefore not documented, it is difficult to ascertain the extent of such critical opinions. In fact, the interviewees did not disclose the content of the critique nor who was criticizing.

All the comments and suggestions to change the text were collected into a single file. Each specific suggestion was taken into consideration and a short comment was added, whether the working group implemented the suggestion.

After the working group had finished the Code, a formal ceremony together with a workshop on research integrity was held. The invitation to adopt the code and sign it formally was sent to all 22 Estonia's nationally accredited research institution and 21 of them signed it, in addition ETAg and the ministry also joined the agreement. The representative of the ETAg indicated the 23 institutions that signed the Code in 2017 were "quite an impressive representation".

According to the interviews, the decision to sign the Code was similar in all the larger universities: it was discussed in senate and then decided by the rector. However, most of the larger universities were already committed to the Code. The representative of the University of Tallinn said that signing the Code wasn't a question, as a member of the university's rectorate participated actively in the working group. It was already more or less decided that the university would sign the Code. She also added that the signing of the Code was probably not widely acknowledged in the university.

The representatives of universities were mostly content with the final Code, the main concern was with the length of the document. The representative of ETAg, however, named several aims that weren't fulfilled. For example, the longer Code does fulfil the educational and awareness raising aims and it also is a national framework that all universities would comply with, however, the ETAg had hoped to achieve more: to raise awareness to a greater degree, to offer training programs and to create an independent committee for handling issues of research integrity.

After the adoption of the code several universities in Estonia continued with developing their own instructions for applying the code. For example, University of Tartu accepted their instructions on 31st of January 2020 and on 1st of April 2020 four research integrity advisors started their work. In January 2020 a report on the Estonian research integrity system that was ordered by ETAg was handed over. In the autumn of 2020, the Ministry of Education and Science has started the process to organize and re-focus the Science and Development Organisation Act and to harmonise it with the aims of the Development Plan of Estonian Research and Development, Innovation and Entrepreneurship 2021-2035. The plan is to complete this process in the beginning of 2023.

From the media monitoring it can be concluded that the Code is rather accepted by the Estonian science community and is used in public discussions, however a report published in the beginning of

2020 indicated Estonian scientists feel the research ethics training needs improvement in Estonia (Espenberg, Juurik, Lõuk, et al 2020). Estonian Code of Conduct highlighted the responsibilities of the researcher as well as responsibilities of science organisation, therefore several universities in Estonia continued with developing their own instructions for applying the Code of Conduct for Research Integrity. CEUT was responsible for developing these instructions for University of Tartu. The process for CEUT lasted about a year and on 31st of January 2020 the senate of the University of Tartu accepted the instructions formally. On 1st of April 2020 research integrity advisers started their work in every faculty (total of 4 advisors). They are coordinated by CEUT. The instructions also state the procedures on filing formal complaints if needed. In addition, the University of Tallinn, the University of Life Sciences and Tallinn Healthcare College have asked CEUT for their help in setting up their own instructions. On national level ETAg has kept their attention of research integrity with ordering an audit on Estonian research integrity systems with recommendations from other countries on how to connect different parts of the system together. In December 2019 the focus of national research conference was on research integrity and the preliminary results of the results were presented by the team of CEUT and Centre for Applied Social Sciences of University of Tartu. In January 2020 the full report was handed over to ETAg. In the autumn of 2020, the Ministry of Education and Science has started the process to organize and re-focus the Science and Development Organisation Act and to harmonise it with the aims of the Development Plan of Estonian Research and Development, Innovation and Entrepreneurship 2021-2035 with focus also on research integrity.

The role of PRO-RES project Working on the project has enabled the team in CEUT to analyse different ethics codes from the values, principles, and standards' perspective (see more Deliverable 1.1, Parder & Juurik, 2019), therefore familiarising the team thoroughly with the topics dealt within the codes. This knowledge was also addressed in the framework of PRO-RES as well as in the Glossary of Terms and Concepts and case studies presented on the PRO-RES website. At the same time the team was incorporating this knowledge to the instructions for applying the Code of Conduct for Research Integrity for University of Tartu. The project also made it possible to analyse the process of accepting the Estonian Code of Conduct for Research Integrity as well as lessons learned from this case study. The competence CEUT has acquired during this project and time provided to analyse the case has made it possible to keep research integrity as a priority between different expectations for CEUT (teaching, public engagement with different groups of the Estonian society). The CEUT team is planning to publish the case study as a science publication. PRO-RES also helped to improve the competence by CEUT in the field of research ethics and research integrity to the next level by providing possibilities to focus on research articles and publish them as science publication (see more Sutrop, Parder & Juurik, 2020; Sutrop & Lõuk 2020). All this gathered knowledge also reflects in the activities performed after the adoption of Estonian code in procedural rules developed for University of Tartu as well as in consultation activities carried out for other RDI-s in Estonia.

4 Lessons learned

4.1 INGSA

The outcome of this deliverable shows three main points:

a) The need for the development of a simple to use framework which would sensitise organisations to work in an ethically sound and methodologically robust environment.
b) The understanding that organisations like INGSA are aware that ethics in research is relevant, but do not see an objective to include ethics conduct codes within their own manifesto or documentations.
c) The relevance reach out to organisations like INGSA who play a crucial role at the interface between science and policy, well beyond the role of scientists and away from the policy makers neutrality to engage with science directly.

This confirms the original view of the PRO-RES Consortium that some organisations or institutions operating at an international level do not see a need to develop their 'own' code for ethics when suitable ones are available elsewhere. Their role is to acquaint members with the availability of codes and guidelines and encourage their use. Different codes and guidelines might be differently appropriate in different cultural/geographical contexts. Members of the INGSA network were invited to send their feedback on the PRO-RES framework and to contribute directly and indirectly to the PRO-RES mid-term conference both directly and indirectly. Their feedback is included in the development of the framework and in the project results.

4.2 UKRIO

What worked well:

The initial drafts were extensive, containing detailed rationales for the key principles, value statements and statements of best practice standards.

There was very strong engagement with the project across the sector, with a large volume of detailed constructive commenting from a wide variety of stakeholders at each draft stage.

What could have been better:

As the drafting progressed, it became clear that the lengthy, fully explicated version was being seen as too unwieldy and concise for easy use by the target audience. In response a condensed version was created and further consultation on this resulted in broad agreement that this summary would be the primary document, with the full version also being made available for reference.

PRO-RES has been promoted through UKRIO and as a consequence of PRO-RES consortium members contributing to this development. The Consortium took particular note of the concern to avoid excessively lengthy and convoluted key documents.

4.3 ESTONIAN CODE OF CONDUCT

Views of the final version of the code: The representatives of universities were mostly content with the final Code, the main concern was with the length of the document. The representative of ETAg, however, named several aims that weren't fulfilled. For example, the longer Code does fulfil the educational and awareness raising aims and it also is a national framework that all universities would comply with, however, the ETAg had hoped to achieve more: to raise awareness to a greater degree, to offer training programs and to create an independent committee for handling issues of research integrity.

The representative of the University of Tallinn hoped that the working group would continue working and finish all the initially planned more specific and practical guidelines and materials. She mentioned she tried to convince others to continue working together on all the issues that the universities were obliged to do after adopting the Code. However, the working group stopped working after the formal adoption of the Code and with this the cooperation among the universities also ended.

The reasons and motivations for creating the code were presented in the documents and correspondence between the working group as well as highlighted later in the interviews reflecting the process. It was stressed both in the documentation and the interviews that the code is needed in order to achieve common understanding on matters related to research integrity. Other reasons and motivations mentioned included educational and awareness-raising, preventive and regulative aim, the need for broader quorum and common understanding and the fact that other developed countries have their code.

From the organisational side, interviews highlighted the process of creating a code of conduct needed to be based on a broad quorum and include representatives from all universities and research institutions that wished to take part or had an interest in research integrity. Because of this, the head of the ETAg visited the Board of Rectors of Estonian universities and invited them to assign their member to the working group.

Research and development institutions (RDI-s) mentioned the need to have common understanding and rules within and between universities in order to agree on the best practices all Estonian universities should comply with and the need for a common understanding and regulations so that every institution wouldn't have to personally come up with regulations, explanations, arguments and solutions to potential problems.

Several issues related to the actual writing process of the code: where to begin, which examples to use, or how long the code should be. One of the first questions that arose was whether the code should be created from scratch or perhaps a translation of an already existing international document would suffice. The main candidate for translation was The European Code of Conduct for Research Integrity of All European Academies (ALLEA). Even though it was decided early on that the Estonian Code should be an original document, the question of translation remained and there was some criticism from the point of view that there are already too many different codes, guidelines, and standards, which apply to research.

Once it was decided that the Code should be written from scratch instead of translating an already existing code, several new questions arose. What should be included in the Code? How to create it in a way it is explanatory but not too lengthy? Which examples to use? Which topics and principles to include? Should the document distinguish clearly wrong misconduct and grey areas? These were all related to the topic of length, which, according to the representative of the ETAg, was "continually on the table". During the meetings it was agreed the code will include important values of science and their explanations, standards, procedures and grey areas.

The final version of the code includes the agreement the partners signed, preface, values (with short explanation for each value) and principles for action divided into five categories: 1) planning of research; 2) conduct of research; 3) authorship, publishing and application of research results; 4) researcher in the research community and 5) observance, promotion and application of research integrity.

The representative of the ETAg, who was also one of the two main initiators of the Code, recalled they had read all the European codes of conduct related to research before the initial meeting of the working group. Two codes – Danish and Dutch national codes – had been chosen for the first meeting.

The Danish Code of Conduct for Research Integrity became the main example for the Estonian code. The Danish code captured simply and clearly the view that not only individual researchers, but also the research institutions and the funding agencies have obligations. The Estonian Research Council also shared this view, which is why the Danish code seemed such a good example to take after.

Other examples included ALLEA, Singapore declaration, different codes of conduct from Europe (Netherland, Finland) and already existing internal documents from Estonian RD-s on one hand in order to find overlapping or already solved topics and on the other hand to find missing or underrepresented topics that need shared approach.

One of the biggest challenges was the translation of English concepts. The term research integrity does not translate too well into Estonian and therefore a suitable term was needed. The working group consulted with an expert of Estonian terminology to gather feedback about the terms and concepts used in the Code. The conceptual challenge was to find an Estonian term that would be easy to understand, convenient to use and at the same time would capture the meaning of integrity. The final translation was *hea teadus* which would directly translate as good science. According to the representative of the ETAg, the other considered designations were honest science and trustworthiness of science. It was also necessary to distinguish research ethics from research integrity as all the discussions in Estonian had previously been only about ethics. According to the representative of the ETAg, it took a few meetings to come to an agreement about the concept of research integrity, what it includes and how to translate it.

In contrast with other case studies, there was a concern that, at a national level, there should be clear 'ownership' and direction for ethics guidelines. But this did not make this an easy mission to accomplish. Motives and commitments vary considerably across a nation and between different professional and disciplinary fields. Once again 'awareness-raising' is compromised by having too lengthy a document – though that in itself has educational/training value. And sustaining a commitment with little obvious personal rewards for the length of time required to produce the document means that the responsibility focuses on a few committed individuals to ensure the mission is completed. The need to include the diversity of interests and methods while also achieving some degree of 'common understanding' is a problem faced by all striving to establish such comprehensive guidelines. A major source of debate when designing a 'new' code from scratch is how much to draw on existing values, principles and standards to be found in the existing codes, how translatable they are to suit the specific Estonian circumstance and how the writing tasks should be assigned.

4.4 SRA

What worked well: The call for volunteers worked well, yielding a diverse group which was reasonably representative of the SRA's membership and the wider social research constituency. The face-to-face meetings were always good, and taking the time to get the revised guidelines right was also important. The meeting with the research ethics expert was very helpful, positive and constructive. The theoretical basis used for the guidelines was a combination of principle-based ethics and virtue ethics. The principles were those from the AcSS and GSR mentioned above. Principle-based ethics alone can seem or become too rigid, and may leave gaps in coverage, while virtue ethics alone risks obscuring the structural factors that can prevent individuals from acting ethically. Combining the two seemed a pragmatic approach to avoiding these problems. This enabled the guidelines to focus primarily on research ethics in the applied, rather than the theoretical, space. This approach has been modified in the final draft, acknowledging that researchers may bring a range of philosophical perspectives to ethical issues. The logistical support for the working group, from the SRA staff and its CEO, were universally praised as being excellent. Beyond this and the involvement of the volunteers there has

been no specific support for the guidelines, as it is work that has gone on in the background, but equally no opposition or criticism was reported.

What could have been better: With hindsight, they would have made the process faster, particularly at the development stage. It was logistically difficult to organise meetings with busy people from around the UK. They sometimes had two or even three months between meetings and they did lose momentum as a result. Also, it could be argued that the call for volunteers worked too well, resulting in a group that was too large to be truly effective. After the smaller group of three took over at the editing stage, the remaining volunteers lost contact with the process. Also with hindsight, the SRA might have paid someone to do the drafting with input from the group, and would certainly have thought long and hard about whether they could do so within the charity's resources. The SRA is a small charity and solvent but not wealthy. The process relied on volunteers and was organised by the SRA's chief executive who is of course very busy as were the volunteers themselves. This in itself caused some problems, such as one chapter being drafted by a single person rather than a pair because one of the two was simply too busy to work on the draft. It would have been useful to have specified the work to be done more clearly at the outset, perhaps with 'terms of reference' including deadlines and ownership. Having different pairs of people drafting different chapters seemed like an efficient use of time and resources, but it led to a situation where the chapters were all very different from each other and standardising the drafts turned out to be a big piece of work. Plus the approach taken from the start meant that a sizeable amount of work done had to be revised and redrafted. Another thing they would have done with hindsight was to talk to people from other organisations who had recently carried out similar exercises to draw on their experience and try to prevent pitfalls.

What could have been different The SRA could have decided to stop providing ethics guidance, and instead have directed its members to the guidance provided by numerous other organisations. However, the previous SRA ethics guidance was found over many years to be very useful for applied researchers, both in its content and its approach which acknowledged that no guidance can cover every eventuality and encouraged researchers to reflect rather than setting a code to govern behaviour. The SRA could have adopted the guidance of another organisation, perhaps through partnering with that organisation. However, it is not difficult to imagine that identifying another form of guidance to adopt could have been an equally lengthy and painful process.

It is important to note that the logistical and organisational challenges experienced are not unique to the SRA. These or similar challenges are likely to be experienced by any institution seeking to produce ethics guidance. We offer this case study in the hope that it will help others to foresee and overcome such challenges.

1) The CEO/Trustees/Executive Board of the professional association should decide the 'policy' for the guidance document from the outset: viz. can it be sanctionable and therefore prescriptive, if not what form should the guidance take and what happens if members are shown not to follow it?

2) Establish an overall editor function - e.g. such as Chair of the Working Party to ensure consistency of style/format.

3) Seek to align with existing guidance in relevant fields - judge whether to simply adopt codes/guidance materials from already established organisations rather than develop one's own: what could be the added value either way?

4) Note the value of the multi-sector membership of SRA - demonstrating it is possible to establish guidance that suits very different sectors. (Though there is a need to handle the potentially conflicting pressures - such as GSR v. public policy research from independents.)

5) Independent advice and expertise should always be sought - and not too late in the process

4.5 AZOP

The findings showed that very few requests about personal data protection from academic and research institutions in Croatia were submitted to the national Croatian data protection authority both before and after the introduction of GDPR. In the second part of the investigation a cross-sectional study was conducted to examine the scope of work, type of work, and education of the more than 700 data protection officers (DPOs) in institutions in Croatia. Results showed that most DPOs indicated that they had no or minimal prior data protection experience when appointed as DPOs. It was concluded that they would benefit from further education/continuing professional development (CPD) on data protection since they currently exhibited insufficient knowledge of basic personal data protection concepts. It was also concluded that job requirements for DPO appointments should be clarified and the certification of DPOs could be introduced as a way of enhancing their role and career prospects.

Fully completed research

a) Future studies could explore whether researchers have sufficient awareness and knowledge about personal data protection related to research, to adequately implement the GDPR regulations. In case that future studies confirm insufficient awareness of GDPR regulations and requirements among relevant stakeholders, interventions both on the national and EU level will be needed to rectify this.

b) Most DPOs indicated that they had none or minimal prior experience in data protection when they were appointed as DPO, that they would benefit from further education on data protection, and exhibited insufficient knowledge on basic concepts of personal data protection. Voluntary certification of DPOS based on the standardized education, provided by the national data protection authorities, should be considered. Continuing education of DPOs needs to be encouraged. Reasons for minimal involvement of DPOs in the work of institutional ethics committees should be further explored in future studies.

c) The majority of Data protection authorities experienced increase in number of requests/inquiries shortly before and after the implementation of the GDPR. There is no standardized education procedure for DPOs on the EU level, however most of surveyed agencies provide some kind of education (courses or workshops) for DPOs.

d) By the spread of the COVID-19 pandemic, initial questions/requests to AZOP related to personal data protection which were associated with potential issues of stigmatisation of individuals suffering from COVID-19 disappeared and were substituted with new questions/requests which were more related to protection of personal health data and population surveillance. In the last phase of the pandemic, AZOP received questions/requests associated with vaccination. This change in the type of requests clearly demonstrated the need for agencies' wide engagement during this pandemic.

e) Personal data protection is one of the most represented ethics categories indicated among MSCA actions, especially after 2018 when GDPR was introduced. This ethics category may exhaust ethics assessment efforts and may lead to "overkills" in ethics requirements. A potential solution to this problem may be excluding the majority of personal data protection assessment from the ethics assessment, except for parts which are directly related to ethics like "Informed consent procedures", in a separate process that should involve specialized experts in personal data protection. A gap in understanding of ethics issues between applicants and reviewers points to the necessity to further educate researchers on research ethics issues.

5 Conclusions

The above studies, along the recommendations and lessons learned from interactions described in PRO-RES deliverables 3.4 (on dialogues with policymakers) and 2.3 (recommendations on the framework), point to a fundamental issue to which the project can give a useful contribution: how to find the elusive optimum between normative (ideal world) and more prescriptive (real world/sanctionable) frameworks for ethics and integrity in research.

In the course of the project, this was found to be a very practical concern, with emphasis put on the importance of the right balance between the concrete guidance and advantage of a short document, as well as the need for good promotion of the framework to ensure that it is applied universally. At issue here is not simply form versus content, but the pragmatic acknowledgement that for ethics to be applied in practice their delivery must have maximal comprehensibility and usability. D3.4 in particular is worth quoting here:

> "There is a wide and strong consensus around the need to provide as many case studies as possible within the toolbox. […] It is crucial that the toolbox can speak a common language and deliver informed material well beyond common approaches in Europe. Case studies – presented as videos, or cartoons or infographics – could convey messages in a more direct way and offer some benchmarking for the user." (p. 19)

On the basis of the feedback given, the challenges PRO-RES faces on account of not being strictly prescriptive have been well exceeded. The support for the STEP Accord exists, and signatories and endorsement are in the process of being sought.

Throughout the dialogues there was ongoing concern that many RPOs (especially in HEIs) tend to have a specialised team dealing with ethics and integrity such that engagement is effectively delegated to this group, with limited reach into the research community itself. Many of our experts comment on seeing grant applications making increasing use of 'boilerplate' statements drafted by these teams without it being clear that the applicants have done any more than cut and paste these to demonstrate compliance. Clearly we are seeking much more engagement than this which seems little more than tokenism.

Hence what also has come through in the course of the project is the role of incentives for implementation of the Accord which might help ensure more depth of commitment. As shown in D2.3, the implementation of the GDPR has helped to bring about a new understanding about the use of data and also a much better attention and awareness to those who constitute vulnerable people. It is clear that all European organisations, both public and private, have to deal with the ethical issue of data management and plan for the conservation, preservation and protection of data, and the role of sanctions that can be given helps to focus minds. People have been hired and trained to engage with the terms of the GDPR and new units and offices have been set to understand the possible consequences of lack of compliance with the data protection regulations.

However, in the context of ethics and integrity for research and evidence gathering the premises of a prescriptive framework such as GDPR are not appropriate. These are concepts in evolution, in constant development, and they are also linked to context and circumstances and thus a prescriptive code would be obsolete as soon as it is provided. For example, the COVID-19 pandemic has changed our understanding of who constitutes *vulnerable people* because, in a global pandemic, anyone may be or become vulnerable due to sickness or bereavement. At the same time, there is a need to navigate across values and principles and to maintain the most robust, coherent framework, bearing in mind transparency and justice as guiding principles, independence and integrity of individuals.

It can be argued that not all relevant agencies even should have the power or ability to sanction. To continue from the example of GDPR, for all its clear benefits, *turning an issue with important ethical underpinnings into a statutory requirement does run the risk that the issue may be seen to fall fully into the purview of lawyers, and not a matter of values, principles, standards and integrity*. In the case of GDPR, the benefits are such as to validate an approach done at a legislative level, but as the case studies and other work done during the project show, things become more difficult when referring to anonymity, confidentiality, consent, etc – that is, concepts which form the core of research ethics.

The PRO-RES project has looked at a range of different agencies in different countries and they have managed to deal with setting up their normative frameworks. Our hope is that the studies and findings above will be found useful not only for researchers into the topic, but in particular for all bodies and associations wishing to establish their own code and/or guidelines. Between the regulatory approaches and purely philosophical issues there lies the field of pragmatic assistance to researchers, who are at the core of any scientific endeavour, and are the end users of the content, that is, the balance to be struck between normative and prescriptive frameworks.

6 Key Points – Recommendations for Code Builders, Adopters and Users

1) Whether at national or professional association level the first key decision is whether to 'adopt' a code or guidelines that have already been established and used, or to construct a code of one's 'own' from the start. This should only be decided after a thorough consideration of the appropriateness of existing codes/guidelines. The case studies in this report demonstrate that constructing a new code is laborious and time-consuming, however so is the process of reviewing existing codes/guidelines and gaining agreement to use one or other of them. Thus before any such undertaking, appropriate resources need to be assigned.

2) If 'adopted' the code/guidelines must be assessed for their 'fitness for purpose' – if at national level they must adapt to all circumstances, settings and disciplines; at professional level they must suit all the situations the professional is likely to confront.

3) If the code/guidelines are to be written afresh, the construction process must be established at the outset. These include: assigning lead author with editorial control; forming a working party to support the lead author (one person alone cannot/should not take on the responsibility); establishing a decision making process for accepting content; conducting desk research that includes decisions about how much of existing codes/guidelines should be incorporated; open acknowledgment of authorship – for credit rather than accountability (the latter being a governance issue – the organisation/institution 'requiring' the code takes responsibility for the final version, its application and use). Organisations may indeed feel the need for their own code for reasons of identity.

4) Buy-in for the code/guidelines is partly dependent upon its 'useability': substantive content and ease of use. The former relies upon the perceived relevance of the content to the users' situation. (Both an adopted code or a freshly written one must be seen to take account of the pragmatics for using it by the primary stakeholders.) Ease of use is governed by length and technical detail – thus it is clearly valuable to have the code/guidelines operating at distinct 'levels' of access:

- L1 – a simple set of statements based upon the key values and principles that can easily be 'signed up to' by the user;
- L2 – a more detailed explanation of the background to the simple signatory statements; and, possibly,

- L3 – an even more detail background to the content and rationale for its existence.

5) Commitment to the code/guidelines is also dependent upon the wider stakeholder community having the opportunity to contribute to its development and (regular) periodic updating. The code/guidelines need to be adequately broadly disseminated such that the user community has full opportunity to contribute suggestions for its improvement. It must remain clear who takes and how they take the final decision on the completed code/guidelines.

6) Whether the code remains at a normative level (advising as to use) or prescriptive (requiring/mandating use) will depend upon the availability of sanctions/punishments for failure to observe the code. If the agency/institution cannot apply sanctions for whatever reason then, for pragmatic reasons, the code should be seen as normative. If sanctions can be applied then they should be proportionate to the failure of observance.

7) Examples of ethical issues which are more difficult to regulate include the ethics of research using social media and the ethics of data analysis. It is important for any code/guideline to offer guidance on the more challenging issues as well as on those that are easier to regulate.

8) Training/education in the content of ethics codes/guidelines should be part of the formal training of all 'evidence-gathering' professionals – researchers, journalists, public relations agents, science advisors and so on. Remaining aware of the key elements of ethics and integrity in practice must remain key to the socialisation process of evidence-gathering professionals. Given the nature of the potential for contextual change, of topic and method, then continuing professional development (CPD) in ethics/integrity in research should be an acknowledged part of career development and rewarded accordingly.

9) Personal data protection (PDP) offers a clear example of an ethical issue that can be regulated more formally. Its effectiveness depends upon: clear regulatory/legislative requirements; the ability to monitor all actions related to PDP (from national to professional levels); adequate penalties for non-observance; the availability of expertise in individuals able to apply the regulations, advise and warn others about their application (hence the key role of data protection officers (DPOs) for the application of the EU's General Data Protection Regulation (GDPR)). The importance of the DPO role for the effective application of personal data protection should be recognised in clear career trajectories, training and professional rewards. The same should be available for individuals involved in the awareness-raising of ethics and integrity in research – such as in helping to write and develop codes and guidelines, in running training events and in serving on ethics/integrity appraisal panels.

10) Formal adoption by the evidence-gathering institution/agency of the final constructed or adopted code or set of guidelines must be established as a key element of its mission.

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