Ethics Assessment of R&D Supported by Standardisation

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DOI 10.3217/978-3-85125-976-6-10

Abstract. Standardisation and standards can be valuable tools for valorisation, commercialisation, and subsequent use of research and development (R&D) results. Furthermore, standards can help researchers in their research in multiple ways, e.g., by preventing them from reinventing the wheel. Most researchers are not familiar with standardisation and rarely use standards in their research projects. How do researchers perceive standards and standardisation? The study aims to analyse researchers' experience with defining the ethical aspects of their research projects (as well as their project proposals) and the perceived usefulness of the framework provided in CWA 17145-1 and CWA 17145-2. Study participants are experienced researchers in writing project proposals and have no experience with standards and related documents. The data collection is based on two-step semi-structured interviews. First, the study explores the researchers' experiences and attitudes on common basic ethical principles, approaches, and practices used by EU-funded R&D projects. In the next step, we inform the study participants about the framework for the ethics assessment of R&D and provide them with documents: CEN/CENELEC Workshop Agreements (CWAs) – CWA 17145-1 and CWA 17145-2. Using a second semi-structured interview, we collect data on researchers' perceptions. The study results provide insight into researchers' perceptions of the usefulness of the CWAs and the framework and their attitudes toward standards (and related documents) and standardisation.

1 Introduction

The European Union (EU) Strategy on Standardisation underlines the importance of standardisation for "Europe's competitiveness, technological sovereignty, ability to reduce dependencies and protection of EU values, including social and environmental ambitions". Furthermore, the success of the Strategy on standardisation will depend on how successful European actors will be in standardisation at the international level (EC, 2022, p. 1). Standardisation can help researchers valorise, commercialise, and use their research results. However, most researchers are unfamiliar with standardisation and rarely use standards in their research. One of the aims of the EU Strategy is to support

researchers from EU-funded research projects to valorise project results through standardisation activities and anticipate early standardisation needs (EC, 2022, p. 1).

The European Commission (EC) published the Code of Practice on Standardisation in the European Research Area with recommendations for research organisations to include standardisation as an important tool for valorising and commercialising research results (EC, 2023, p. 1). According to the Code of Practice on Standardisation in the European Research Area: "Standards help researchers and innovators bring their innovation closer to the market and spread technological advances by establishing uniform criteria and by developing methods, practices, and procedures publicly available in a formal document. European and international standards provide access to large global and regional markets for innovative new products and services" (EC, 2023, p. 1).

Several initiatives are active to support the research projects funded by the European Commission. HSbooster.eu is a 24-month European Commission initiative that will provide the European Standardisation Booster. The booster offers expert services for European projects to help them increase and valorise project results by contributing to the creation or revision of standards. HSbooster.eu facilitates and streamlines the dialogue between Horizon 2020 (H2020) and Horizon Europe (HE) research and innovation projects with the standardisation landscape and its main actors, namely corresponding Standards Developing Organisations (SDOs) to increase the European impact on international standardisation and strengthen the European competitiveness.

Standards can be defined as "a widely agreed way of doing something" (Abdelkafi *et al.*, 2021, p. 5). A standard is "a construct created by a meaningful, reasonable, and collective choice that enables agreement regarding the solution of existing problems" (Cargill, 2011). However, not all research results are solutions suitable for standards. In most cases, for researchers engaged in R&D projects that have developed innovative solutions in some fields, standards are not an appropriate way to disseminate project results because these solutions need time to reach a satisfactory level of technology stability (CEN/CENELEC, 2020, p. 7). Within standardisation – no matter its type (e.g., is it formal or informal standardisation, is it recognised by law or states, or is it consortia-based standardisation), one cannot do very much alone. A new solution must be of certain market readiness to reach targeted and interested stakeholders who could support the common agreement on specific solutions at standardisation comities.

To answer researchers' needs regarding standardisation, European organisations for standardisation CEN/CENELEC have developed "standards-light-like instruments" which do not require complete stakeholder consensus regarding the solution given in it. These instruments are called CEN/CENELEC Workshop Agreements (CWAs). CWA is a "CEN and/or CENELEC deliverable developed by a Workshop, which reflects an agreement between identified individuals and organisations responsible for its contents"

(CEN/CENELEC, 2022, p. 9). A CWA can take a different form, such as a text file or code, and it is developed to meet an urgent need of the stakeholders interested in the issue (CEN/CENELEC, 2020, p. 5). Therefore, the time for the drafting document is short; it usually takes 6 to 12 months to have a published CWA by CEN/CENELEC Members. CWAs are established to deal with tasks specified in their project plan and separated from Technical Committees (CEN/CENELEC, 2020, p. 7). A developed CWA can be proposed for conversion into a European standard to a Technical Committee. If they approve the proposal, the CWA must go through the standard development process by the rules of CEN/CENELEC (CEN/CENELEC, 2020, p. 7).

Each R&D EU-funded project must define the ethical aspects of its research projects (as well as its project proposals) in its project documentation and research activities during the project's lifetime. But the question is, which project participant or participants will do an ethics assessment of a project proposal, or will all do it? Or would they engage consultants with expertise in ethics to deal with these issues on their project? Another side of the medal is whether there is support such as good practices, e.g., some already developed (and endorsed) frameworks which could help them address ethical issues. Finally, the critical question is whether standardisation could support the ethics assessment of R&D, e.g., with a common ethics assessment framework given in CWA.

2 Literature Review

Compared to traditional research ethics which gained momentum after the Second World War (and the Nuremberg Code), both theoretical and empirical discussions on the ethics assessment of research and innovation (R&I) commenced during the 1990s (Reijers *et al.*, 2018). Various studies on the ethics assessment of R&I have emerged ranging from engineering sciences (Riley, 2013) and business studies (Bose, 2012), emerging technologies (Brey, 2012b) and ICTs studies (Brey, 2012a) to biomedical sciences (Winkler, Hiddemann and Marckmann, 2011) and nanotechnology studies (Viseu and Maguire, 2012). Zwart et al. (2014) have studied legal and social aspects of the ethics assessment of R&I. Reijers et al. (2018) analysed 35 different methods for ethics assessment based on the various stages of the R&I process. Additionally, the ethics assessment of R&I may "manifest itself in formulations of R&I project-specific codes of conduct or checklists of ethical issues and principles; also, it can take the shape of ethicists joining in the design process of new technologies and innovations, and of researchers and stakeholders engaging in a collaborative setting" (Reijers *et al.*, 2018, pp. 1438).

At the European level, ELSA studies covered ethical, legal, and social aspects of emerging sciences and technologies (Zwart, Landeweerd and van Rooij, 2014). ELSA concept which dates back to the Fourth EU Framework Programme (1994-1998) must be distinguished from ELSI which refers to ethical, legal and social implications of emerging life sciences, notably human genomics, a program funded by NIH/NHGRI (Zwart, Landeweerd and van Rooij, 2014). Also, Responsible Research and Innovation (RRI) studies emerged, being part of the projects funded by the European Commission (Burget, Bardone and Pedaste, 2017). Drawing upon the Sixth Framework Programme (2002-2006) – "responsible research" emerged aiming to address "ethics: networking between existing bodies and activities, promotion of dialogue in a global context, awareness raising, training, research on ethics in relation to science and technology; and uncertainty: risk and the precautionary principle: analysis and best practice" (European Commission, 2002, pp. 10). Based on the Seventh Framework Programme (2007-2013) – "responsible research and innovation" emerged and evolved as a part of the Regulation EU No (1291/2013) establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (European Commission, 2021).

Over the years, both ELSA studies and the RRI literature much as its antecedents (such as bioethics) "have triggered scepticism and criticism from various corners" (Zwart, Landeweerd and van Rooij, 2014, p. 8). Comparing ELSA studies and RRI – both streams argue that "scientific expertise cannot be deemed as the sole basis for the development of new technologies; conversely, society should be involved early on" (Burget, Bardone and Pedaste, 2017, p. 3). Additionally, both streams have been enforced by policy-makers and not the research communities which may be one of the reasons why the EC publications have been cited vigorously, especially within the RRI literature (Gwizdała and Śledzik, 2017). Although "ELSA bears a striking resemblance to RRI" (Burget, Bardone and Pedaste, 2017, p. 2) – Von Schomberg (2012, pp. 16) argues that "RRI sees ethics as a stimulus, not an obstacle", suggesting that "what's new about RRI is that we no longer see the ethical aspects of new technologies as constraints, as restrictions. Instead, we look at the aims of technology development. Which positive contributions do you wish to obtain from research and innovation? This positive basic attitude is an important difference in comparison with the ELSA approach" (Von Schomberg, 2012, quoted in Zwart, Landeweerd and van Rooij, 2014, pp. 13). Additionally, the same author (pp. 16) suggests that "RRI rebels against the more traditional approach (which was focussing on the question whether a development has undesired effects), but rather uses the possible positive contributions of [...] a technology as an assessment criterion [...] unlike ELSA, RRI considers the entire innovation process, from research and development to production or distribution" (Von Schomberg, 2012, quoted in Zwart, Landeweerd and van Rooij, 2014, pp. 13).

Although a lot has been done to address the ethics assessment of the R&I projects funded by the European Commission, the European Commission is currently working on addressing several questions concerning the ethics assessment of the R&I projects. To date, several EU-funded R&D projects had developed CWAs, such as – MODENA, SATORI, SMR, DRIVER+, EPOS, SMARTER TOGETHER, COROMA, BRESAER, BIONIC AIRCRAFT, VOLATILE, MONSOON, UNICORN, REACH2020, WISEGRID, ETIP OCEAN 2, SEA-TITAN, etc. One of the projects on ethics assessment of R&I titled "Stakeholders Acting Together on the ethical impact assessment of Research and Innovation – SATORI" (www.satoriproject.eu) which was funded by the EU aimed at summarising the descriptions of the ways in which ethics assessment of R&I are currently practised in different scientific fields, in different European countries, but also China, and the US, and also within different types of organisations (Brey *et al.*, 2017). Additionally, the project offered a common framework for the ethics assessment of R&I consisting of common basic ethical principles and joint approaches and practices that are supported and shared by all the main stakeholders involved in the design and application of research ethics, ethics of technology and innovation standards and principles (Brey *et al.*, 2017). As a result of the project, two CWA (i.e. pre-standard) documents have also been drafted and approved by a Workshop and endorsed by CEN members:

1. CWA 17145-1:2017, Ethics Assessment for Research and Innovation – Part 1: Ethics Committee and
2. CWA 17145-2:2017 Ethics Assessment for Research and Innovation – Part 2: Ethical impact assessment framework.

Both parts of CWA should be used to enhance the ethics assessment of R&I and are "of interest to organisations or agents who are involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues" (SATORI, 2017). Both parts of CWA are a result of a consensus-based multistakeholder process ("but quicker and less rigorous than with a full standard") and are developed when existing procedures and best practices in ethics assessment were translated into a practical tool for anyone who would like to enhance ethics assessment (SATORI, 2017).

While Part 1: CWA 17145-1 gives recommendations on the ethics committee members (their roles and responsibilities, competencies, appointments, composition, etc.), ethical issues and principles, procedures, and quality assurance in ethics assessment (CEN, 2017a), Part 2: CWA 17145-2 describes the ethical impact assessment framework, alongside guidance on conducting the ethical impact assessment threshold analysis, ethical impact assessment plan, ethical impact identification, ethical impact evaluation, remedial actions, and review and audit of the ethical impact assessment (CEN, 2017b). While Part 1: CWA 17145-1 applies to "ethics committees, institutional review boards,

ethical review committees, ethics boards, and units consisting of one or more ethics officers, regardless of size, scope, and research and innovation area" (CEN, 2017a, p. 5), Part 2: CWA 17145-2 applies to "all researchers and innovators, regardless of the context they are working in or their research and innovation area" (CEN, 2017b, p. 6).

Given that "all organisations or agents who are involved in performing, commissioning or funding research and innovation, … have a responsibility to address ethical issues" (CEN, 2017a, p. 6) – the key Research Questions (RQ) that our study seeks to answer are –

RQ1: How do researchers perceive the main obstacles during the ethics assessment of R&D projects?

RQ2: What are researchers' attitudes towards using standards-like documents – based on their perception of the CWAs for the ethics assessment of the R&D projects?

3 Methodology

3.1 Sample

Our sample included researchers with experience in writing research proposals and participating in EU-funded R&D projects. We interviewed a total of 15 researchers from the University of Belgrade with experience in R&D projects (usually from 1 to 10 years). Most interviewed researchers are males (73%), and the rest (27%) are females. Also, the research areas covered with the projects are Business, Economics, and Finance; Political Sciences, Information Technologies (IT), Artificial Intelligence (AI), Machine Learning; Statistics and Mathematics; Strategic and Performance Management; and Circular Economy.

3.2 Data Collection

Two separate semi-structured interviews were used to collect empirical data. The first part of the interview was used to collect data regarding researchers' experiences and attitudes on common basic ethical principles, approaches, and practices used by EU-funded R&D projects (in which they participated) and how they perceive the main obstacles during the ethics assessment of R&D projects. In the next step, we inform the researchers about the framework for the ethics assessment of R&D and provide them with CWA 17145-1 and CWA 17145-2. The second part of the interview questions was used to collect data on researchers' perceptions of the usefulness of the CWAs and the framework and their attitudes toward standards (and related documents) and standardisation.

3.3 Data Analysis

The qualitative content and relational data analysis proceeded in three steps: (1) the identification of critical incidents and codification of responses provided by the respondents, (2) the analysis of content and relations and (3) the clustering of the codes into groups.

4 Results and Discussion

4.1 How do researchers perceive the main obstacles during the ethics assessment of R&D projects?

Although all our respondents have participated in preparing multiple project proposals, not all have gained experience in the ethics assessments of R&D projects, suggesting that the ethics assessment and information related to ethical aspects of R&D projects were not deployed among all members of the consortia. Five of our respondents denied any obstacles. The perceptions of other participants suggest the following results:

- Ethics assessment of R&D should consider uncertainty in research and science. Our respondents claim:

  "The main obstacle is that scientific outcome is unpredictable and, in most cases, novel (compared to other business areas where one can promise and deliver an outcome). Thus, any issue that arises should be related to a similar (not the same) issue in the past to assess the situation".

  "Another obstacle is the fact that ethical issues are sensitive, and any decision made influences an individual much more than other common violations".

- Ethics assessment is perceived as a legal issue (e.g., *"main obstacles were searching for the appropriate regulations that the project is mandatory to follow"*) or an administrative issue (e.g., *''ethical board provided me with all documents I needed"* or *"there was no transparent procedure when applying for projects"*).
- Ethics assessment is perceived as a burden. Four respondents mentioned ethics assessment's administrative aspect, claiming it is all about *"bureaucracy"* or *''administrative procedures".*
- Ethics assessment of the R&D projects is perceived as someone else's job. It can be seen in statements, such as: *''During the writing of the project proposal, the principal investigator used personal contacts and contacted an expert in the field*

of ethical assessment to help us complete the part of the project documentation related to ethical assessment" and *"it should be provided institutional or private help in doing the ethical assessment".*

Our results confirm that societal needs are mostly underestimated, and that scientific expertise dominates decision-making in R&D projects consortia. In this context, our study provides results similar to those of Burget, Bardone and Pedaste (2017). The need to involve society early in the research process can be fulfilled in many ways. The following research question can provide us with more insights into the question wheather the standards (or standards-like documents) are suitable for this task.

4.2 What are researchers' attitudes towards standards-like documents based on their perception of CWAs as a tool for the ethics assessment of R&D projects?

Our respondents perceived standards and standardisation differently. Researchers from social sciences and statistics perceived standards (standardisation) as positive. Some examples of their statements are:

- *"By standardising the ethics assessment process, standards can help to promote consistency and transparency in decision-making, which can enhance the credibility and legitimacy of R&D".*
- *"Standardisation can be beneficial for the ethics assessment of R&D projects".*
- *"Any standardisation and framework is a good starting point for assessing various needs".*
- *"Framework is very useful for project implementation in various research areas. Its uniformness is its biggest advantage".*
- *"Standards and standardisation are extremely important for the ethics assessment of projects since they provide the informative framework for evaluating the ethical issues in conducting the projects".*
- *"Standards in EIA can improve assessment significantly".*

Practical explanations in the Annex E of CWA are particularly positively perceived (e.g., *"methods for ethical impact analysis given in Annex E of CWA 17145-2 is valuable for EIA"*).

However, our respondents would like to see the document in a more practical shape (*"It is a valuable tool for EIA but should be made available via an Excel sheet (at least) to the general population"*).

Also, researchers from technical disciplines (such as ICTs or physics) doubted that one solution could fit all. These researchers seem reluctant to widen their interest in their other activities, and they are highly attached to their own disciplines. For example:

- *"It largely depends on the project topic(s). EIA is more useful in some specific projects (e.g., those related to people, animals, drugs...), but can be less useful if the project is related to quantum physics".*
- *"All the proposed documents are very useful for project management and principal investigators. However, I am sceptical that a principal investigator from a field such as IT or Engineering is qualified to use standard and complete the proposed assessment adequately".*
- *"Standards should be domain specific since some questions are unrelated to all the research areas".*

The free spirit of scientific research is seen as opposed to standardisation, as our respondent claims: "*Strict formalisation of the scientific process is negative, as science requires more time and experimentation to produce an outcome compared to business uses*". This seems to suggest that our respondents did not quite understand the issue at hand because it's not about constricting research but about providing a universal tool to evaluate aspects of it. However, the question still remains. Does one size fit all?

Our respondents agree that standards and standardisation can be valuable tools for valorisation, commercialisation, and subsequent use of research results. However, most researchers (especially the ones from mostly technical disciplines such as ICTs) are not familiar with standardisation and rarely use standards in their research projects which is why their perception of the framework provided in the CWA is mostly negative.

Maybe the solution lies (as always) in education (and training) about standardisation – standards are not enough and several researchers perceived the need for education and training: *"One needs a guidance document(s) and proper education to foresee the effects of the research and intervene if needed"* and *"it would be of greater usefulness to educate the ethical committees at faculties or universities to help researchers in these steps, review the ethical assessment [when] done and provide feedback to the PI and PM".*

Although (formal) education about standardisation should be seen as the starting point for acquiring knowledge, skills, competence, and experience in standardisation matters – researchers involved in R&D projects need continuing education (life-long learning). Still, education (and training) about standardisation must find its place in both formal education and life-long learning to have standardisation professionals who can use their knowledge about standards for valorisation, commercialisation, and subsequent use of their research results and not rely on somone else to do the standardisation work.

There seems to be a misunderstanding between researchers involved in R&D projects on who should do the ethics assessment which is why it is perceived as a legal issue, administrative issue, a burden, or someone else's job. If this continues to be the case, the ethics assessment will be done poorly or will eventually remain completely undone. If we understand the ethics assessment of R&D as a process or a path, that process must begin somewhere, and standardisation (and standards) might just be that place.

5 Conclusion

Our study aims to provide more evidence on how researchers perceive standards based on the case of the ethics assessment of R&D projects and CWA 17145-1:2017 and CWA 17145-2:2017.

Our findings give insights into the different perceptions regarding the main obstacles during the ethics assessment of R&D projects. Our respondents perceive the ethics assessment in R&D as a burden, as someone else's job, as a legal or as an administrative issue, and they argue that it should consider uncertainty in research. Our results confirm that societal needs are usually underestimated, and that scientific expertise dominates decision-making in R&D project consortia. In this context, our study provides results similar to those of Burget, Bardone and Pedaste (2017). Also, the need to involve society early in the research process can be fulfilled in many ways. Our results suggest the presence of stakeholders' asymmetry, the phenomena that focus on research results (topics) which might blur the impact on different stakeholders (Mahoney *et al.*, 2022).

Our findings reveal that our respondents perceive standards and standardisation differently. Our respondents usually don't have experience in using standards and standardisation to support the ethics assessment of R&D. Still, after introducing them to CWA 17145-1:2017 and CWA 17145-2:2017, we found that most of them perceive the given framework as useful. Regarding their attitudes toward standards (and related documents) and standardisation, most social sciences and statistics researchers perceive standards and standardisation as positive, but others felt that standards were insufficient.

Our results reveal that researchers perceive standards in the context of promoting consistency and transparency, enhancing credibility and legitimacy, providing uniformness, and being informative. However, some of our respondents would like to see the standards' recommendation in a more practical shape – like an Excel sheet. Our study reveals that researchers from technical disciplines doubt that one solution would fit all and perceive standards-like documents (CWA) as too generic and not easy to follow,

and they also need training or guidance to use these document(s). A negative perception of standardisation is observed in the context of "strict formalisation" and the need for more time for experimentation to produce an outcome compared to business uses.

Our results suggest that making standards and standardisation closer to researchers should be done in several ways: first, by making them familiar with the basics of strategic aspects of standardisation, second, by making standardisation closer to them (in their core disciplines), and third, by underlining the impact of standardisation on the limitation of stakeholder asymmetry.

The limitations of our study are based on the sample and the fact that all participants come from the University of Belgrade. Continuing our study, we will tend to enhance our sample with researchers from other faculties and universities, and other countries. Also, as the European standardisation system differs significantly from the system in the USA or China, our future studies could involve researchers from not only Europe, but the USA or China, and the comparison between these standardisation systems (and the researchers' experience with defining the ethical aspects of their research projects) could be conducted. Considering that the ethics assessment and information related to ethical aspects of R&D projects are not deployed among all members of the consortia, different members of the consortia have different attitudes and perceptions – our future studies could examine the perceptions of several members from consortia (or consortia as a whole) as this might be significant for standardisation practitioners and experts in the field.

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