proEthics

Deliverable

D5.2 PRO-Ethics Framework 1.0

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1 Executive Summary

PRO-Ethics aims to develop a framework that guides the ethical design and implementation of participatory processes, addressing different contexts, resources, and needs. The way participation is conducted, how it is based on regulatory frameworks, and to what extent ethical issues are taken into account can differ significantly across contexts. At the same time, concerns over non-traditional stakeholders (e.g., citizens and NGOs) and their potential contribution emerge along new modes of open innovation. Accordingly, PRO-Ethics develops an ethics framework that provides guidance to ensure stakeholders' participation is properly executed without disregarding values such as fairness, transparency, equality, and privacy.

The *Ethics Framework 0.1* was the first operational outcome of PRO-Ethics, offering a set of **reflections, tools and guidelines** to assess the ethical aspects of participatory processes. Building on previous theoretical work (*Theoretical Framework*) and empirical work (*Report on Mapping of current practices of RFOs*[1] *in Europe*) undertaken in PRO-Ethics, this *Framework* combines these findings with additional insights from Pilot I preparation activities undertaken in the first year of PRO-Ethics.

The *Ethics Framework 0.1* was empirically tested and further improved in the subsequent years, both within the PRO-Ethics Pilots, and beyond, gathering feedback from civil society, researchers, research funding organisations, and other stakeholders that finds interest in designing and implementing participatory processes. The combination of these activities has led to the final *Ethics Framework 1.0*.

The aims of the *Ethics Framework* are: to provide orientation and legitimacy to participation; to ensure participatory processes are meaningful, both for participants and organisations; and to guide the design and implementation of participatory processes, taking into account ethical aspects, prior, during, and after the stakeholder participation. As such, it operates as **a tool for reflection and justification** and a reminder of ethical aspects to consider. The *Framework's* first part is descriptive in nature, providing information on the general background, scope and objectives. It furthermore elaborates on experiences with the *Framework*. The second part forms the core of the *Framework*, offering guidelines to be used as a roadmap.

As participation requires significant resources (both human and financial), the need for guidance to design and implement processes that are legitimate forms an issue that needs to be addressed. In order to do so, the participation's added value must be clarified, while notions of accountability and transparency shape the boundaries of the *Framework*. Taking a step back to analyse the grounds on which participatory processes can be ethically designed and implemented connects with the need for guidance and indicators.

As each context is unique, this *Framework* provides general aspects to consider, setting common denominators aimed at covering **main ethical considerations and requirements addressed by any participatory process** in R&I. The tools and guidelines provided consist of:

i) taxonomies and definitions (Glossary H);
ii) questions and "actions" to be undertaken.

The taxonomies relate to stakeholders and forms of participation processes, in order to specify whom or what is targeted under the notions of "stakeholders" and "participation". In addition, the questions to be addressed before, during, and after the participatory processes aim to ensure ethical aspects are adequately addressed, from design until ex-post assessment. These questions cover: the design of the participatory process; the type of activity that is targeted for participation; the selection of participants; the ethical issues and risks, and how to address them; the fostering of equal and meaningful dialogue; and the monitoring of, and reflection on, the participatory process.

The Framework is to be used for the design, implementation, and completion of participatory to ensure ethical concerns are addressed at each stage. It subsequently offers considerations regarding its usefulness as **its added value is not self-evident**. This *Framework* can be used as a reflection tool and roadmap to systematically support decisions. It highlights key questions that help decide when ethical expertise is insufficient and should be sought externally.

[1] Research Funding Organisations.

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2 Introduction

The *Ethics Framework* consists of tools and guidelines with a focus on how stakeholder participation can be properly organized without disregarding ethical principles of fairness, transparency, equality, and privacy. Aspiring to address ethics of participation in the context of Research and Innovation (R&I), this *Ethics Framework 1.0* aims to operate as a standard for organizing stakeholder participation, and how to address ethical issues and risks. Taking stock of difficulties surrounding ethics and participation in R&I[2], **this *Framework* provides information on how to deal with a diversity of views on ethics and participatory processes, and the diversity of practices of research funding organisations (RFOs).**

This version of the *Framework* draws from all previous work undertaken to this stage — both at the theoretical and at the empirical level. The research done in PRO-Ethics under the lead of Sciences Po and the Delft University of Technology has highlighted assumptions and needs that this *Framework* attempts to address. The *Paper manuscript on participatory practices and ethics issues in R&I*[3] is a state-of-the-art report on ethics and participation, that emphasised the **blurred vision** that the R&I literature and practices showcase in regard to participation. In response, this study opened up different meanings of participation and offers **a multi-layered approach, combining theoretical considerations with empirical insights**.

As regulations are limited, this deliverable **combined legal resources with scientific literature (from Social Sciences and Humanities studies)** to bridge the gaps. It concludes that three decades after the inception of (participatory) technology assessment, essential **questions remain unresolved: as to why, how, and in view of what quality participatory processes are undertaken.** This urges us to consider unresolved aspects, which the *Framework* attempts to address: how is participation justified; what are the goals/outcomes targeted; and what are the underlying ethical issues? In addition, this study finds that all participatory processes should determine who is affected, interested, or can contribute to solutions in light of the time and resources available.

This *Framework* is furthermore built on the *Report on Mapping of current practices of RFOs in Europe*, which combined: i) a **survey** with 10 organisations from the PRO-Ethics consortium (8 RFOs and 2 organisations that are partially operating as important funding organisations); and ii) 11 **interviews** with European experts in ethics and/or participation. Hence, combining data, leading to a comprehensive view on practices, contexts, definitions, and expectations. It revealed the **diversity of practices and understandings among actors**. More specifically, it emphasised the profound differences on a more abstract level in how to approach the ethics in, and of, participation. It revealed national and sectoral discrepancies in RFOs' practices and expectations. This *Report* furthermore revealed disagreements on the need for formalised standard procedures for evaluations across EU countries. Moreover, it found that the citizens and end-users are underrepresented in current participatory practices.

The *Framework* also draws from the Eureka[4] case study: the *Report on the treatment of ethics in Eureka,* that presents a **comprehensive analysis of the treatment of ethics** within its network. This study focused on the funding tool of Eureka's case study: "Eurostars"[5], Eureka's flagship programme. This report provides an overview of Eurostars while showcasing the role of participants and ethics experts in the ethics review.

In addition, other inputs have contributed to the *Framework*: the PRO-Ethics Pilots preparation, the cross-pilot workshops, IT tools workshops, and internal ongoing discussions among the fifteen European organisations involved in PRO-Ethics. Overall, this consortium has highlighted the need for: a shared definition of participation and ethics; an understanding of the ethical dimensions we address; a better recognition of ethical issues and risks, and how to deal with them; a checklist of considerations for involving participants; and a thorough reflection on ethical challenges, biases, and the aforementioned

[2] See the PRO-Ethics *Theoretical Framework* (deliverable D1.2).

[3] Also known as "Theoretical framework" (see previous reference).

[4] Eureka is an international public network, present in over 45 countries; it has been established in 1985 to foster European competitiveness and integration and to encourage R&D&I cooperation.

[5] Eurostars is a joint programme (of Eureka) with the European Commission that funds collaborative international R&D&I projects, based on a bottom-up approach.

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considerations. In addition, issues were identified regarding conflicting interests, methods, and knowledge during participatory processes.

Lastly, the *Framework* draws on research done by the Delft University of Technology and Sciences Po on the experiences of RFOs with the *Framework*[6]. This resulted in various lessons learned that made the *Framework* more actionable, reflecting the needs and abilities of RFOs.

This *Ethics Framework* is PRO-Ethics' main deliverable. It was implemented and tested within PRO-Ethics activities (Pilots) before reaching its final version. More than an internal tool, this *Framework* aims at broad dissemination and adoption: it operates as a **roadmap** for RFOs, providing important ethical features that are not context specific. As such, the *Framework* provides questions and steps that cover all stages of participatory processes – from the design and development, to the evaluation of stakeholder participation. Thanks to its format and scope, this Framework responds to different contexts of implementation, providing key topics and questions to be addressed to **determine whether an ethical participation process is possible, and how it should be structured in view of different factors**.

This *Ethics Framework 1.0* consists of two parts:

i) a general description (theoretical introduction) explaining the context of use, scope, objectives, and positioning of this *Ethics Framework*, and how it should be used;

ii) tools, guidelines, and a glossary, of which the latter presents taxonomies and definitions. The tools and guidelines take the shape of a leaflet to make ethics more actionable. These offer "actions" to be implemented, addressing main ethical considerations. **This list of questions should be asked before, during, and after the implementation of participatory processes**. These tools and guidelines are written for a broad audience, beyond Europe, and beyond RFOs.

Determining the type of participatory process requires considerations of the relevant perspectives, actors and outcomes. Stakeholder participation can take many forms and subtle distinctions have to be embraced in order to **specify the conditions under which stakeholders are invited to participate.**

[6] Wiarda, M., Giannelos, K., & Doorn, N. (Forthcoming) Stakeholder Participation and Research Funding Organizations: Difficulties and Countermeasures

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3 Part I: General Considerations

3.1 On Ethics

3.1.1 General considerations on ethics

Although some requirements for ethical stakeholder participation are covered by ethical compliance, other ethical consideration may give rise to tensions. Indeed, ethical expertise is required to cover all ethical issues and risks. Yet, ethical guidance may be ineffective once innovations are developed and embedded in society. Scholars therefore urge for early and anticipatory ethical deliberations to collectively shape innovation when this is still possible[7].

Considering the **complexity and unpredictability of innovations**, the concept of responsibility should be a key dimension in R&I. This stance serves to prevent that R&I processes are considered "irresponsible", often the results of misunderstanding the (importance) of innovations' societal context, leaving (value) conflicts unresolved (e.g. lack of precautionary measures, or neglect of ethical principles). The concept of Responsible Research and Innovation (RRI) has emerged as an extension of the Science in Society discourse about the embedding of solutions, (upstream) engagement[8], and reflexive governance[9]. Accordingly, ethics cannot be reduced to standard procedures and legislation only (soft law, ethical compliance). Ethics should be considered a field (from applied ethics to meta-ethics[10]) that extends the regulatory schemes: **ethics helps decipher legitimacy, tensions, and adequacy of processes and legal compliance in regards with contextual criteria**.

The **pluralism of moral theories** suggests that there are several rational paths that can be followed in regard to ethics assessment (in justification context): types of entities assessed (i.e. action, person, institution, technology) from a normative perspective; normative factors (i.e., values, consequences, virtues or norms); foundational normative theories (ways to select normative factors and types of entities). Conflicting factors or hybrid forms of reasoning call for a move beyond regulations (as in ethics review/assessment), and to embrace a broader pluralistic scope. These views demand an enhanced reflexivity and responsibility, the latter being subject to different understandings.

3.1.2 Ethical assessment procedures and the *ethics review*

Given the **precedence of ethics over positive law and regulations**, ethical compliance and appraisals such as ethics reviews, are not comprehensively covering ethics but are rather closer to legal standards and regulations. Publicly funded R&I is associated with an advanced set of ethics assessment procedures, safeguarding the compliance of research with ethical principles. However, ethics review processes differ across countries, as such procedures are not systematically implemented in funding programmes supported by the European Commission. The impact of ethics reviews[11] differs per project, sector, and country. The European regulatory landscape reveals gaps and difficult relationships between ethical practices and participatory practices. The connection between ethical practices and participation remains underdeveloped, as their link is often unspecified.

On a wider scale, ethical considerations and practices require skills and knowledge that researchers and innovators usually lack. Ethical analyses require the identification of ethical aspects; familiarity and

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[7] Van den Hoven, J. (2014): Responsible Innovation: A New Look at Technology and Ethics. In M. J. Van den Hoven, N. Doorn, T. Swierstra, B. Koops & H. Romijn (Eds.), Responsible Innovation 1: Innovative Solutions for Global Issues. Dordrecht: Springer, pp. 4-7.

[8] Wilsdon, J., Willis, R. (2004). *See-through Science: Why Public Engagement Needs to Move Upstream*. London: Demos.

[9] Owen, R., et al. (2012). Responsible research and innovation: From science in society to science for society, with society. *Science and Public Policy*, *39*(6), pp. 751-760.

[10] Reber, B. (2016). Precautionary Principle, Pluralism and Deliberation: Science and Ethics. London/New York: ISTE/John Wiley & Sons.

[11] The ethics review process takes place in the assessment of R&I project proposals within European funding schemes. This procedure has been established in 2011, when proposals have been identified as raising ethical issues, that are further examined by a panel of experts.

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conformity with standards; and an understanding of approaches to build, recognize, and justify ethical dilemmas in light of conflicting values. The notions of "right" and "wrong" are based on moral values (ideals), or principles and norms that define standards – identified as "ethical principles", some concerning individual rights, benefits, harms, fairness principles, and virtues. Identifying ethical issues provides guidance for R&I processes, a reflection on implications, an enhancement of transparency and accountability, as well as better processes. As such, **ethical expertise provides tools to address the complexity and unpredictability of innovations, enhancing responsibility within R&I processes**.

The concept of responsibility can either refer to the legal, moral, or social sphere. Sometimes considered as a term for responsibility, the precautionary principle[12] is fundamentally anticipatory and "does not allow uncertainty on the scientific side of assessment to be used as an excuse when serious presumptions of significant and/or irreversible damages have been made"[13]. Studies highlight the importance of technology assessments and the uncertainties involved. Indeed, "uncertainty" relates to several aspects: the unawareness of implications, the insufficient understanding of their frequencies, forms, and severities; and the ignorance vis-à-vis interrelated ramifications.

3.2. On Participation

3.2.1 General considerations on participatory practices

Participation, as part of public engagement, is a crucial part of the Responsible Research and Innovation (RRI) "keys". Participation is a complex and contested notion on itself in light of various supporting and opposing normative, substantive, and instrumental rationales. Participation is not always deemed desirable and is often opposed by those who consider that scientific work is already exposed to many constraints both internally and externally (e.g. international competitiveness).

The *Framework* is aligned with the Sustainable Development Goals (SDGs), following the European Commission's policy approach to innovation, which promotes the "Three Opens": "Open Innovation", "Open Science", and "Open to the World" [14]. The notion of openness responds to the assumption that "we live in a time when those without access to the traditional establishment are often the ones doing the most exciting work" [15]. The participation of non-traditional stakeholders relies on normative democratic rationales that justify different approaches, outcomes, activities, and timelines [16]. It furthermore stems from a loss of public trust — a democratic deficit particularly salient in the current science-society relationship — where participation springs up as a remedy. Participation is furthermore supported by substantive rationales that assume that tackling complex public problems requires collective decision-making to foster better outcomes[17].

Public concerns regarding the impact of emerging technologies are embedded in the grounds of participatory processes, enabling stakeholders to discuss any aspect of R&I. **Despite thirty years of participatory technology assessment, issues on participation such as "why?", "how?", and according to "what quality?" are not yet resolved**[18], which arguably weakens the legitimacy of participation.

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[12] The precautionary principle has been first embedded in European policy in the 1992 Maastricht Treaty for environmental policy; it has expanded to other fields of policy under EU law, where it intervenes as provisional risk management measures that have to be considered to prevent adverse effects. See the *PRO-Ethics Paper Manuscript on Participatory Practices and Ethics Issues in Innovation* (D1.2).

[13] Reber, B. (2018). RRI as the inheritor of deliberative democracy and precautionary principle. *Journal of Responsible Innovation: Responsible Innovation and Brain, 5*(1), p. 40.

[14] Bogers, M., Chesbrough, H., & Moedas, C. (2018). Open Innovation: Research, Practices, and Policies. *California Management Review*, *60(2)*, p. 11.

[15] Carlos Moedas' speech "Lund Revisited: Next Steps in Tackling Societal Challenges", Lund, 4 December 2015. In European Commission - Directorate-General for Research and Innovation (2016). *Open Innovation, Open Science, Open to the World*, p. 97.

[16] PRO-Ethics deliverable D1.1 *Report on Mapping of current practices of RFOs in Europe.*

[17] Fung, A. (2008). Democratizing the Policy Process. In R. E. Goodin, et al. (Eds), *The Oxford Handbook of Public Policy*, Oxford: Oxford University Press, pp. 681-682.

[18] See Pellé, S., & Reber, B. (2016). *From Ethical Review to Responsible Research and Innovation.* Hoboken: ISTE/ John Wiley & Sons, chapter 2.

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The connection of participation with ethics has several layers of complexity as there are various participatory procedures, goals, and connections to responsibility[19]. There are different perspectives on ethics, governance tools (ethics committee, participative or deliberative devices, etc.), understandings of responsibility, and types of inclusion (e.g. participation or deliberation, the decision-making powers of the stakeholders involved). Participation can be justified by different understandings of responsibility in relation to the process and outcomes of R&I, bearing a variety of meanings.

As such, participation has different goals, approaches, and relationships with decision-making. For example, possible approaches include: citizen juries, consensus conferences, deliberative conferences, the Delphi and Charette methods, focus groups, planning committees, scenario workshops, "visions of the future" consumer workshops, global cafés, opinion polls (with or without deliberation), questionnaires, citizen advisory committees, vote conferences, interactive technology assessment (TA), constructivist consumer TA, ad hoc committees relating to the rules of negotiation, interdisciplinary work groups and political role play. The participation's relationship with decision-making may also differ since reaching an agreement could materialise under consensus, compromise, or other forms, including consent to disagreement. In technology assessment, ten goals of participatory processes can be outlined: assessment of consequences; extension of perspective for R&D policies; agenda setting; mapping public scientific controversies; more interactive surveys; coverage of arguments; reframing of debates; mediation; policy recommendations (for new technological fields); and comparison of new governance forms.

Who participates is another key issue of participation. Targeted participants are usually identified as "citizens" or "stakeholders", which are not synonyms, nor covering the whole array of potential participants. There can be various participants including the general public (lay people) and civil society, next to the conventional participants (scientists and experts). PRO-Ethics includes a wide spectrum of participants, while acknowledging that contexts differ in terms of what participants are considered relevant.

Moreover, lacking a definition of what proper processes are, may lead to poor forms of participatory processes. **As there is no single definition of participation, PRO-Ethics opens up the meanings of participation to embrace the whole array of practices.** While there is no single best participatory approach, a clear distinction of activities, timelines, expected outcomes, and participants can provide a common reference. Hence, **the use of a common taxonomy and indicators as presented in this *Ethics Framework* are part of the guidelines and are meant to be used as a common tool**. Reaching a rich form of participatory processes requires clarifying questions, such as which participants should be included or excluded, and the nature of decision-making (e.g. majority, unanimity, veto right). Richer forms of participatory processes are found in deliberative models, promoting public participation through iterative processes and fair representation ideals. Deliberation is a participation form in which dialogue, engagement, and justifications are developed to respond to essential democratic requisites, reflecting the theory of deliberative democracy.

PRO-Ethics identified several needs of research funding organisations (RFOs). These relate to the definitions of participation and ethics in R&I; the ethical dimensions and issues; the ethical risks and their mitigation; the need for checklists specifying what to consider when involving participants; and the considerations regarding ethical challenges, bias, and points of attention. Furthermore, specific issues have been identified on conflicting interests, methods, and type of knowledge. Subsequently, participation should be understood through a case by case approach, asking adequate questions, and considering different contextual options.

3.2.2 Characteristics of current participatory practices

European RFOs share several common ethical aspects. However, not all consider ethics in their participatory processes, owing to a variety of national specificities of structural and procedural nature, and different capacities and competencies[20]. While stakeholder participation is often considered a high-

[19] The following indications on procedures, goals, and levels of responsibility mentioned in this paragraph are extensively analysed in: Pellé, S., & Reber, B. (2016).

[20] See the PRO-Ethics *Report on Mapping of current practices of RFOs in Europe* (deliverable D1.1).

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priority objective, RFOs do not always have the structural means to develop participatory processes. Stakeholder participation mostly occurs before and during R&I, even though its importance for after R&I (e.g. impact assessment) is widely acknowledged. Stakeholders participation can create conflicts of interest while not all RFOs have the competencies to address this. Indeed, the interests of stakeholders have to be analysed and navigated.

The perceived benefits and legitimacy of participatory processes differ among stakeholders. There are various characteristics that play a role in participation such as: the means and needs of RFOs, the modes of participation; and the ethical challenges and issues of participation critical to RFOs (identification and representation of participants, avoidance of biases, use of personal data, etc.). All aforementioned insights from the critical review of legal, regulatory, and institutional frameworks regarding stakeholder participation were used to develop the tools and guidelines in this *Ethics Framework*.

3.3. Experiences with the Ethics Framework

Several RFOs experimented with the *Ethics Framework* for their stakeholder participation processes. Collective reflections on its practical use revealed difficulties and best practices that may prove valuable for future participatory processes. These lessons learned related to the: recruitment of participants; managing commitment and expectations; fostering of dialogue and equal participation; accommodation of vulnerable groups; creation of funding themes with participants; lack of expertise in participatory ethics; and planning, flexibility, and resources. In what follows, this section elaborates on some of the key insights that emerged from the RFOs' experiments with the *Framework*.

RFOs indicated difficulties in relation to **the recruitment of participant**. RFOs generally aim for a heterogeneous group of participants that embody the appropriate representation of stakeholders. Nevertheless, it remains difficult to determine what stakeholder representation is appropriate. RFOs selected stakeholders on various aspects, for instance, on their social background, education, age, religion, ethnicity, and gender (identity). But this likewise posed challenges when considering the intersectionality of participants; a participant may identify with multiple stakeholder groups. A possible way forward is to allow stakeholders to categorize themselves according to their own ideas regarding their identity. In addition, the 'right' representation tends to be understood differently among stakeholders. The context-dependent nature of participatory processes provides that such challenges cannot be addressed in a standardized manner. However, RFOs can consider whether representations that reflect society are desirable, given that the politics among participants will then likely reflect the dynamics found in society. It may, for instance, be desirable in some cases to give minorities an enhanced voice to mitigate power imbalances. RFOs furthermore wrestled with the recruitment of the targeted stakeholders as these were not always willing to participate. RFOs therefore relied on feasible solutions such as snowball sampling and the support of multiplier organisations to compose a group of participants, while acknowledging the drawbacks of such methods (e.g. selection bias).

Managing commitment and expectations posed challenges as stakeholders have different ideas on R&I, RFOs, and their participatory processes. Experiments suggest it is important to understand and accommodate the needs of participants. Some stakeholder may require different forms of participation, or may need financial compensation. It proved helpful to transparently communicate everyone's expectations regarding the purpose, process, and outcomes of the participatory process. Such aspects can, for instance, be made explicit in a code of conduct.

Various difficulties emerged during the participation process in relation to **organizing dialogue and equal participation**. Because stakeholder participation is frequently characterised by diverse perspectives, it poses the risk of misinterpreting each other. In addition, equal participation is deemed important to obtain all relevant values and worldviews. However, some participants dominated discussions as a result of their personality, knowledge, and institutional role (e.g. citizen vs. scientist). Deploying a skilled mediator may help to mitigate imbalances and involve less vocal participants. It may also help to reduce information asymmetries by either offering or withholding information.

RFOs indicated challenges related to **the accommodation of vulnerable groups**. This is especially relevant as participatory processes in research funding often relate to solving real-life problems. The stakeholders affected by these problems may therefore be subject to social injustice, financial issues, or other disadvantages. Because vulnerability is difficult to define and understand, it can help to

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consider aspects that give rise to stakeholders' vulnerability such as their resources, abilities, experiences, identities, values, and worldviews. Stakeholders generally have a better idea of their vulnerability. Hence, it can be beneficial to directly ask stakeholders' perspectives on this as opposed to the RFO making this judgement by itself. RFOs could also help accommodate vulnerable groups based on their own suggestions, and by compensating for the underling aspects that give rise to disadvantages, e.g., through financial compensation, the use of translators, or the enhanced accessibility of meetings.

In the case of **stakeholder participation for the creation of funding themes/priorities**, some RFOs experienced difficulties determining how to involve both conventional stakeholders (scientists and innovators) and non-traditional stakeholders (e.g. citizens). RFOs recognized three possible ways to involve them: (1) conventional stakeholders can propose themes, and non-traditional stakeholders can select and contextualize these; (2) non-traditional stakeholders propose themes, and conventional stakeholders select these; or (3) the proposition and selection is done collectively. While it remains unclear what approach is most meaningful, RFOs found that collective discussion can give rise to power imbalances (e.g. based on expertise and status). Allowing non-traditional stakeholders to propose themes provided many socially relevant themes, but where not always considered scientifically relevant. Allowing conventional stakeholders to propose themes, while non-traditional stakeholder selected them appeared most fruitful as this led to scientifically and socially relevant themes. Yet, the appropriate approach likely remains context-dependent.

While skills and knowledge on ethics is believed to improve stakeholder participation, **RFOs frequently lacked ethical expertise**. It is therefore helpful to understand that organizing stakeholder participation benefits from a learning-by-doing type of approach that is flexible and open to feedback from it participants. RFOs suggested that the *Ethics Framework* helps, but that external support from ethicists can further foster the quality of participation.

Lastly, it is important to stress that **while the *Ethics Framework* strives for the highest ethical standards, this may not always be possible in practice**. Organizing stakeholder participation is an uncertain process that tends to unfold differently than planned. One RFO mentioned that "these processes seem way more resource consuming than thought in the beginning". Participatory processes are furthermore dependent on external factors (e.g. regulation and operational planning). All these challenges provide that it is helpful to have a surplus of resources available, and to have back-up plans in case flexibility is required.

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4 Part II: Tools & Guidelines

Considering the inherent complexity resulting from the connection of participation with ethics, how should participation be organised and framed? Rather than providing a list of criteria only, **this *Ethics Framework* offers a broad list of questions that should be addressed,** and which encompass criteria, classifications and reflections to be undertaken. The purpose of the PRO-Ethics Tools & Guidelines is to provide a roadmap in the form of questions following which, the design, the implementation and the evaluation of R&I processes, participatory practices can be tailored in accordance with the specificities of each context. Because different contexts offer different opportunities and constraints, **this *Framework* functions as guidelines rather than rigid rules.** In the criteria, taxonomies and considerations presented below as part of the main questions, there is no hierarchy of participatory processes. The different sections below are **addressing main ethical considerations and questions helping to determine the participants and the participation modes**: who? when? how? and what for?

The consideration of these questions is meant to define how stakeholders can be invited to participate in R&I processes, both according to an **ethical approach** and with an **added value**. In that vein, ethical issues are guiding these tools, comprising a list of dimensions and questions to address in order to have **a roadmap for the diversity of methods and options of participatory approaches**. Considering that there is no universal ideal solution but principles and norms to be contextualised, the purpose of this *Framework* is to provide tools and guidelines to decide upon whether ethical participation is warranted and what actions and considerations should be undertaken in order to reach it. Since participation is not taken for granted, **this *Framework* suggests taking a step backwards and discussing our very assumptions regarding participation**. The most suitable participatory path in each specific case derives from the combination of the context and the specific needs both of the institution undertaking it and of the R&I process that it is applied to. Although this *Framework* is designed for RFOs, it may likewise prove valuable for other organisations.

Below, we offer a set of questions and associated actions to consider when designing, implementing and evaluating a participatory process:

A. How should participatory processes be structured?
B. Which type of activity is targeted by the participatory process?
C. Which types of participants are targeted?
D. What are the ethical issues and risks?
E. How can equal and meaningful dialogue be fostered?
F. How should participatory processes be monitored and reflected upon?

Each of these sections includes timeline indications, that are visually highlighted in the box of each specific subset. These indications serve to identify when a specific action is to be undertaken: these timelines may be cumulative in the case of an iterative action (at different stages):

- ***before*** participation (design phase of the participatory event);
- ***during*** participation (implementation of the participatory event);
- ***after*** participation (feedback following the completion of the participatory event).

Also included is a glossary of key terms frequently used in the context of participation in R&I processes, to help develop shared understandings and a common language to discuss these topics.

These guidelines are intended to guide the design, implementation and follow-up of participatory processes in accordance with an ethical approach, as a common roadmap encompassing all types of participatory activities and participants. As such, these guidelines may be relevant for researchers, call programmers, or scientific/ethics evaluators, for instance. The structure of these guidelines offers common steps and considerations that form a common ground of questions and actions to undertake.

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A) How should participatory processes be structured? *[before]* *[during]* *[after]*
▸ ***Action A1: Identify and clarify the expected contributions.*** *[before]*
Identify why you are interested in certain types of knowledge and perspectives. This allows for a focused design of discussions and ensures that the overall intention of the participatory process is framed, justified, and outlined. In addition, be aware that potential participants likewise have assumptions that may need to be addressed. Transparently clarifying these in a code of conduct helps align expectations.
▸ ***Action A2: Allow for flexibility when planning the participatory process.*** *[before]* *[during]* *[after]*
R&I processes should be interconnected with the design of the participatory process. Organizing stakeholder participation is often characterized by learning-by-doing. Unexpected nuances and concerns of participants may reveal themselves during the project. Organizational flexibility is therefore helpful. Participatory processes should hence allocate (more than) enough resources to the participatory process. These resources and the selected participatory methods[21] contribute to flexibility and therefore require explicit consideration.
▸ ***Action A3: Explore impacts of R&I processes and design a participatory process that relates to these concern.*** *[before]* *[during]*
This action aims to address social, economic, environmental, cultural, political, legal and scientific concerns. Impacts can be best identified in inclusive manners, and can be better understood by involving those stakeholders that are potentially affected. Impacts should be listed and related to the (design of) the participatory process.

B) Which type of activity is targeted by the participatory process? *[before]*
▸ ***Action B: Define for which type of activity a participatory approach is undertaken.*** *[before]*
After outlining and structuring the above-mentioned intent, flexibility, feedback loops, and impacts, an appropriate participatory process has to be selected (see below), in terms of type and timing of interaction. The type of process chosen furthermore depends on the stakeholders' relationship and potential contribution to the R&I process. Possible contexts for participatory processes are: • **Stakeholder engagement in research funding** • **Stakeholder engagement in innovation projects** • **Stakeholder engagement within agency's processes** • **Stakeholder engagement in evaluation processes** Several types of activities are possible, such as:[22] ○ **General consultation** ○ **Evaluation** (of projects) ○ **Information/knowledge sharing** ○ **Monitoring** ○ **Programme design** ○ **Social impact evaluation** ○ **Project execution**

[21] Regarding the diversity of participatory methods to choose from, please refer to section 3.2.1 (above).
[22] The definitions of this classification are to be found in the Glossary (last section of this *Framework*).

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C) Which types of participants are targeted? *[before]*

- ***Action C1: Determine which stakeholders to engage and why, followed by interlinking the participatory process, context, and stakeholder types.*** *[before]*

The actor categorisation is important both from the perspective of the general distinction of categories and also regarding their proximity with the R&I process[23]. These two specifications allow for a better identification of groups that may have been overlooked, and different types of participants that may require a different treatment. In order to accommodate the needs of actors, it is helpful to better understand their backgrounds prior to stakeholder participation. This preliminary identification ensures that the type of participatory process is compatible with the context and the stakeholders involved[24].

- ***Action C2: Determine how actors should be recruited, taking into account stakeholder representation, selection bias, and feasibility*** *[before]*

After potential participants are identified, it is crucial to consider how these can be best recruited, taking into account both stakeholder representation, selection bias, and feasibility. While recruitment can be challenging, stakeholders are more inclined to participate if the process is in their direct interest. Practical approaches/mediums for recruitment are:

- **The RFO's network:** The existing stakeholder network of the organizer provides the opportunity to recruit participants. Stakeholders can for example be contacted through social media or newsletters.
- **Snowballing techniques:** Asking participants for referrals to other potential participants can enlarge the existing pool of participants.
- **Multiplier actors:** External actors (e.g., municipalities, intermediaries, and influencers) can help recruitment efforts by providing access to their stakeholder network. Persuading these multipliers to collaborate tends to be easier when they share similar interests with the participatory process.

D) What are the ethical issues and risks? *[before]*

- ***Action D: Identify the ethical issues, and tackle them appropriately.*** *[before]*

Once the participatory process and participants are defined[25], potential ethical issues should be considered to determine the need for an adaptation of the participatory process. Ethics experts can help identify, understand, and mitigate ethical issues.

Consider the following potential issues in relation to your R&I processes:

- **In project proposals:** Issues of human dignity, privacy, and data protection, transparency, and biases (e.g. gender bias) should be considered when planning the process and outcomes of research and innovation.
- **In project execution**: Issues relating to: personal data; discrimination; stigmatisation; fixation on technology acceptance; vulnerable groups; privacy; safety; social responsibility of researchers; social roles in the application context; use of ethically sensitive findings; manipulation and guardianship through technology.
- **In evaluation processes:** Common ethical risks in relation to stakeholder's legitimacy, lack of ethical expertise; communication of funding calls.

Consider the following issues that may return in general:

- ***Conflicting interests:***

[23] See previous section (B), above.

[24] In particular, the balances between roles of researchers and stakeholders should be taken into account, so as to properly address research integrity issues (in the event of conflicting views, for instance).

[25] See section B and section C (respectively).

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- Avoid conflict of interests (conflicts with existing funding structures and processes; or internal conflicts related for instance to doubts regarding the planned participatory process);
- Strive for a diverse representation of stakeholders;
- Identify potential issues of legal capacity (impartiality; partiality; external conflicts).

- ***Methods:***
  - Consider that when participation is made a mandatory requirement for funded projects, this raises the hurdle for diverse and new institutions to access funding;
  - Identify the level of adequacy of the selected participatory process, in regard to: i) if participation is warranted in the given project; ii) if the involvement of participants would benefit from adequate support;
- ***Knowledge / awareness:***
  - Consider what resources and dissemination strategy are needed to help participants understand R&I. For example, participants should be given enough time to process information;
  - Identify what knowledge is needed (scientific/technical background) for the participatory process; foresee what type of group dynamics may emerge as a result of information asymmetries; and ensure that potential ethical problems that have been spotted find the required expertise.
- ***Disadvantaged stakeholders***
  - Identify which, and how, stakeholders are disadvantaged.
  - Engage with disadvantaged stakeholders prior to the participatory process to understand their needs.
  - Customize participatory processes to disadvantaged stakeholders' so that they can participate in a meaningful way.
- ***Scientific integrity:***
  - Identify if (and how) participatory process might affect the researchers?
  - Align the participatory process with the scientific community and their values.

E) How can equal and meaningful dialogue be fostered? *[before]* *[during]*

▶ ***Action E:*** Consider how equal and meaningful dialogue can be established and safeguarded in light of the participants' vulnerabilities and characteristics. *[before]* *[during]*

Ensure that the design and implementation of participatory process foster equality in, and meaningfulness of, dialogues between participants. Try to foresee what forms of representation, participant types, and reciprocal relationships are applicable, taking into account expected power imbalances and the desirability hereof. The following non-exhaustive list of considerations are important:

- **Representation:** Consider who is excluded and included by reflecting on the balance between diversity and representation (proportionality); composing a set of participants while taking into account the possible (over)representation of minorities.
- **Power:** Make sure all participants are heard, and try to reduce power imbalances. These imbalances may result from the participants' differences in personality, ability, knowledge, and resources. It can, for instance, help to reduce information asymmetries by providing or withholding information. In addition, try to identify (potential) conflicts that need to be navigated.

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- **Exploitation:** When including minorities and vulnerable stakeholders, ensure that they are not disproportionally burdened with the participatory process. If needed, provide forms of compensation either before, during, or after the process.
- **Vulnerability:** Recognize that there are many aspects to vulnerability that are often difficult to identify. Pay specific attention to aspects that give rise to vulnerabilities such as one's experiences, abilities, identity, resources, values and worldviews. Participants themselves know best whether they are vulnerable. Trust their judgement and accommodate adequately for their vulnerability.

F) How should participatory processes be monitored and reflected upon? ***[before]*** ***[during]*** ***[after]***

▸ ***Action F1: Monitor and collectively reflect on the participatory process and outcomes.*** ***[before]*** ***[during]*** ***[after]***

To safeguard ethical aspects of participation, it is important to monitor critical factors during the process' implementation and evaluation. This can be done through the use of performance indicators, and through continuous feedback from participants. Continuously and collectively reflecting on (un)expected performances and outcomes helps improve current and future participatory processes. Expectations may be adapted if needed, following a possible deviation from pre-set monitoring indicators[26].

▸ ***Action F2: Reflect on the following aspects.*** ***[after]***

- Verify if matters of representation and inclusion were addressed throughout the participatory process;
- Consider input from participants in the final decisions of participatory processes;
- Take into account the justification of participation to link the quality and functionality of participation with societal needs.

▸ ***Action F3: Launch a transparent process allowing participants to interact.*** ***[after]***

Depending on the size of the participatory activity and the organisational capabilities, a collective reflection on the participatory process helps to learn about the participants' experiences. This feedback should be used as the main assessment of the process, indicating potential needs for improvement.

▸ ***Action F4: Communicate how the input of participants is used.*** ***[after]***

Reflect on the input of participants, its added value, and how this did (not) feed into outcomes. Communicate this with participants, and ensure they feel valued. In some cases, this may include a financial compensation or an official acknowledgement.

▸ ***Action F5: In view of future reference, all reflections answering the Framework's actions could be saved.*** ***[after]***

Future participatory processes can learn from the current stakeholder participation when monitoring and archiving answers to the above-mentioned actions. It furthermore supports matters of accountability.

[26] This action is complementary with A2 and A3 (see above, section A).

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H) Glossary

The following glossary encompasses terms that are being frequently used to describe:

- several categories in which a person/group can fall;
- the type of activity of participatory processes;
- general terms of interest;

The categories and definitions outlined below reflect the work undertaken in PRO-Ethics and serve as common references. **These categories are part of the "classifications" in the Tools & Guidelines** of the present *Ethics Framework*.

Citizens

This category includes the general public, lay people, and citizens as persons (or collectives) with civic expectations[27]. Moreover, since end-users can be categorized as citizens as well, this distinction serves to underline the general dimension of involvement, referring to the broader sense of "public participation". This category may also relate to a broad participatory approach.

Consultation

Processes of engagement with any group of citizens or stakeholders, in order to obtain feedback on policies and programmes.

End-users/consumers

End-users/consumers are defined as a specific category distinct from citizens (sometimes with overlaps), referring to beneficiaries of the end product (including solutions and services) of the R&I process. This category specifically refers to the impact and the uses of the products of R&I activities in society.

Engagement

Information and knowledge about research and innovation (R&I) activities can be provided and disseminated (e.g. dissemination of research to public), thus raising awareness on R&I activities (e.g. through media, science festivals and open days at universities and research centres).[28]

Ethics and Integrity

Integrity refers to research findings and the process in which they are produced (i.e. data, methods, interpretation and presentation/reporting) and whether such processes and findings meet established and appropriate scientific, legal and professional standards. By comparison, "research ethics" pertains to the moral issues that occur in the research design and its implementation, for instance in relation to the protection of humans, animals, environment, data as well as the proper protection of other objects.[29]

Evaluation (of projects and programmes)

This category encompasses several types of evaluation: evaluation of project proposals (i.e. the ethical and scientific evaluation) as part of the selection process intervening in funding schemes; the interim and ex-post evaluation for projects and programmes that received funding; and programme evaluation.

Experts

[27] In this category, the main boundaries for the "citizens" category are anchored in the citizens/stakeholders distinction.

[28] Source: https://www.invo.org.uk

[29] Source: ENRI Network Braun R., Ravn T. et al. (2019) RE/RI expert set of indicators for e-database. ENRI Deliverable 6.2.

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This category serves to identify individuals enrolled as (internal or external) experts in RFO activities, but at individual level and not as part of any of the other categories. Therefore, lay experts for instance can be included in this category, if their involvement mainly values their expertise (as citizens) and if this category prevails over others (e.g. "citizens"). Experts can be individuals with any sectoral expertise (e.g. with a background in medicine, psychology, sociology, philosophy — among others).

Information/knowledge sharing

Dissemination of information on R&I contents, outputs and scientific knowledge. Also one-way as the communication of funding activities, knowledge sharing relates to the dissemination of scientific content only. This mostly related to one-way engagement towards any type of public, and the sharing of information related to communication of funding activities (funding portfolio) and/or funded activities (the funded R&D&I and its results).

Involvement

Citizens and stakeholders can be actively involved in R&I activities: for instance as patients, as grant holders and co-applicants, identifying research opportunities, agenda setting, or as members of project advisory and steering group, in co-developing of patient information or materials, or undertaking interviews with participants, and carrying out research.[30]

Monitoring

The systematic follow-up of funded projects in the context of RFO funding schemes is usually an activity carried out internally (but which can be supported by external experts: e.g. when doing interim or final reviews), although ex-post monitoring of results can involve other actors, in addition to the involvement (feedback) of programmes' beneficiaries.

Organised civil society

Civil society organisations have different knowledge and leverage than individual citizens. They may defend interests, often professional interests (trade unions), or causes (e.g. animals, environmental issues), or rights (e.g. minorities, women).

Participants

Participants are defined as persons who take part in participative processes. These persons might be: citizens without a specific interest in the case (referred to as "citizen participation"); (end)-users with a specific interest in the results (also part of "citizen participation"); stakeholders including non-traditional stakeholders as NGOs with specific knowledge and/or specific interest (not part of "citizen participation") and with any level of engagement and interaction. Furthermore, participants can be either individuals or representatives of institutions or groups (organised civil society) and may include vulnerable groups such as patients, children, or older adults. In each case, the kind of participating persons should be carefully described.[31]

Participation

Citizens and patients take part in research and innovation studies (e.g. as patients being recruited in clinical trials; completing questionnaires; participants in interviews and focus groups).[32]

Programme design

In the context of research and innovation, programme design refers to the identification of programme objectives and of R&I priorities, resulting in the definition of funding opportunities.

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[30] Source: https://www.invo.org.uk/

[31] Source: PRO-Ethics D5.1

[32] Source: https://www.invo.org.uk/

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RFO

Research Funding Organisations

RFO activities

In the context of PRO-Ethics, RFOs´ activities (processes) refer to programme/funding scheme development, and implementation (launch of the call, reception of proposals, proposal selection), as well as strategic planning (including grants/programme management). The processes might also refer to: e.g. organisational concepts and personnel development but proposal selection is a core process of an RFO, thus treated as a separate category.

Scientists/research institutions representatives

Individual scientists (any scientific or technical field) or representatives of research institutions, involved in RFO processes either for their individual expertise or for their affiliation to a research institution, but speaking for themselves only. In case they are invited on behalf of a private company conducting research, these participants should be identified as part of the "private bodies" category. This category also includes researchers meant as physical persons working for a legal entity (SMEs, Universities, Research Institutes) conducting research and to whom has been granted public or private funding to do so. Participants under this category can be considered as "Experts".[33]

Social impact evaluation

RFO activities that aim at measuring societal impact of R&I processes, including the development of indicators and the monitoring allowing such measurement.[34]

[33] Source: PRO-Ethics deliverable D1.1 (op. cit.)
[34] Source: ibid.

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