proEthics

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D1.4 PRO-Ethics Ethics Framework 0.1 and Guidelines

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1 Executive Summary

PRO-Ethics aims at the elaboration of a framework ensuring citizens and stakeholders' participation can be properly designed and implemented, addressing different contexts, resources, and needs. The ways participation is conducted, how it is based on legal and regulatory frameworks and to what extent ethical issues are taken into account can differ significantly across countries and contexts. At the same time, concerns over non-traditional stakeholders (such as citizens or NGOs, for instance) and their potential added value emerge along with new modes of innovation and open R&I configurations. In this respect, PRO-Ethics develops an ethics framework with principles, guidelines, and tools that can provide some guidance and a roadmap to ensure citizens and stakeholders' participation is properly put in place without disregarding principles of fairness, transparency, gender equality, privacy, and sustainability.

This *Ethics Framework 0.1* is the first main operational outcome of the PRO-Ethics project, offering a set of **reflections, tools and criteria** to assess the ethical aspects of novel interaction modes in research and innovation (R&I) activities. Building on all previous findings in PRO-Ethics, from the theoretical work (*Theoretical Framework*) and empirical work (*Report on Mapping of current practices of RFOs*[1] *in Europe*) undertaken, this draft *Framework* combines these findings with some additional practical insights brought from Pilot I preparation activities undertaken in the first year of PRO-Ethics activities.

This first version of the *Ethics Framework* of PRO-Ethics is meant to be empirically tested and further improved in the course of the next two and half years, both within the PRO-Ethics Pilots, and beyond, gathering feedback from civil society, industry representatives, researchers, research funding organisations, R&I public and private institutions, and all public or private stakeholders that may find an interest in the development of guidelines and criteria in view of designing and implementing ethical participatory processes.

The aims of this *Ethics Framework* are: to provide orientation and legitimacy to participation, addressing also some practical issues in implementing participation; to ensure participatory processes are meaningful both for participants and organisations; and also to certify the design and implementation of participatory processes takes into account all main ethical aspects that need to be addressed, prior, during, and after its completion. As such, it operates as **a tool for reflection and justification** and a reminder of main ethical aspects to consider. The first part of this *Framework* is of descriptive nature, providing information on the general background, scope and objectives; the second part is the core part of the *Framework*, with the synthesis of guidelines and recommendations to be used as a roadmap.

As participation requires a significant amount of resources (both human and financial), expertise, and commitment, the need for guidance and tools to design and implement processes that are both adaptive and legitimate is an issue that needs to be addressed. In order to do so, the underlying guiding question of the added value of participation has to be addressed, while notions of accountability and transparency towards participants will shape the boundaries of the present *Framework*. Taking a step backwards to analyse the grounds on which participatory processes can be ethically developed and conducted appears as a requirement that connects with the need for guidance and indicators.

Each context having its own specificities, this *Ethics Framework* only provides orientations and opportunities to consider, setting some common denominators aiming at covering **all main ethical considerations and ethical requirements addressed by any participatory process** in R&I. The tools and guidelines provided consist of:

i) taxonomies and definitions;
ii) a list of questions with related "actions" to be undertaken.

The taxonomies relate to participation actors and participation activities, in order to specify what or who is targeted under the broad notions of "citizens" or "stakeholders" and "participation". In addition, a list of questions to be addressed before, during, and after the implementation of participatory processes aims to ensure all main ethical aspects are adequately addressed, from the design until the

[1] Research Funding Organisations.

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ex-post assessment. These questions cover: the design of the participatory process; the way to address the classifications provided; the main ethics issues and risks and how to properly identify and address them; the anticipation of critical factors that may arise in specific contexts; the monitoring and evaluation of participatory processes; and the identification of the added value of participation both prior to and after the implementation.

This Framework is to be used for the design of participatory processes, during the implementation, and after the implementation, in order to ensure some main ethical dimensions are addressed at each stage. In this respect, it consists of a common reflection base that provides guidance for the proper adaptation of participatory processes. It also allows for flexibility and enables reflection on the reasons why participation is considered in the first place, and if it is an appropriate tool to use in a given situation — as **its added value is not taken for granted**. This *Framework* can be used as a reflection and assessment tool, as well as a roadmap helping to keep track of the decisions taken in a consistent manner. In this regard, it highlights some key questions that can help decide when ethical expertise is insufficient and should be externally sought, as well as how or which participatory features should be considered, and the reasons why a participatory initiative is considered in the first place and the way it relates to the wider societal context.

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2 Introduction

The scope

The present *Ethics Framework* consists of principles, guidelines, assessment criteria, good practice and proposals on regulatory environments with a focus on how citizens' engagement can be properly put in place without disregarding ethical principles of fairness, transparency, gender equality, privacy and sustainability. With the ambition to address ethics of participation in the context of publicly funded Research and Innovation (R&I), this *Ethics Framework 0.1* aims to operate as a common standard on how to deal with the diversity of views and how to properly address ethical issues and ethical risks to be used both in top-down and bottom-up approaches. In this perspective, it is aimed to operate as a common reference on ethics of participation for policymakers, funders and civil society. Taking stock of the theoretical difficulties that surround the lack of joint framing of ethics and participation in R&I[2], **this *Framework* aims to provide information on how to deal with the diversity of views on ethics and participatory processes, and the diversity of practices on behalf of research funding organisations (RFOs), both in terms of legal and structural means.**

The background

This first version of the *Ethics Framework* draws from all previous work undertaken to this stage — both at the theoretical and at the empirical level — among PRO-Ethics consortium partners. The previous research that has been produced in PRO-Ethics under the lead of Sciences Po has consistently outlined the main 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 overall **blurred vision** that R&I literature and practices showcase in regard to participation. To tackle this, this study opened up all possible meanings of participation and tried to offer **a multi-layered approach, combining theoretical considerations with policy-making and empirical insights**. As regulations were particularly limited, this deliverable **combined legal resources and soft law with scientific literature (from Social Sciences and Humanities studies)** in an attempt to bridge the gaps. A main conclusion of this report is that as of now, and 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.** These findings urge us to consider some aspects that remain **unresolved**, which the present *Framework* attempts to address: how is participation justified; what are the goals/outcomes to be targeted; and what is the nature and scope of the underlying ethical issues? In addition, other findings from this previous study that are to be found here are that all participatory processes have to determine who is affected, interested or can contribute to actual solutions, as part of the criteria of ethical legitimacy for any given participatory process, while at the same time, the timescale and the resources of participation have to be examined as well.

A second study that this *Framework* has built on is 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 experts who have been chosen across Europe for their expertise in ethics and/or participation. These **two layers of analysis** have led to a different treatment of data: a qualitative analysis through an RFO survey in the first case and semi-structured interviews for the second one, leading to a comprehensive view on practices, contexts, and also expectations. This study aimed to try and understand the variety of definitions of the terms "citizen", "stakeholder", "participation", and "ethics". It highlighted the **diversity of practices and understandings among different actors**, both for ethics and for participation. More specifically, the data collected also emphasised the profound differences on a more abstract level in how to approach the ethics in and of participation. It also revealed national and sectoral discrepancies both in current practices of RFOs and in their expectations as well, regarding the future development of their practices. This *Report* also revealed

[2] See the PRO-Ethics *Theoretical Framework* (deliverable D1.2).
[3] Also known as "Theoretical framework" (see previous reference).

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unequal national support to RFOs in terms of means and expertise allocated to ethics and participatory activities. An additional particular insight that has been brought forward specifically through the expert interviews was the disagreement over the need for a formalised standard procedure for evaluation across all EU countries. Moreover, other conclusions from this study have shown the discrepancy between the expectations of participatory processes and their current limited development: for instance, the actual involvement of citizens and end-users in current participatory practices presents a comparative underrepresentation.

A third study that the present *Framework* also draws from is the Eureka[4] case study: the *Report on the treatment of ethics in Eureka* presents a **comprehensive analysis of the treatment of ethics** within its network. This study focused on the funding tool at the centre of Eureka's case study: "Eurostars"[5], Eureka's flagship programme, and also its first programme having integrated the ethics review in its evaluation procedures. This report provides a general overview of the Eurostars funding programme while it also turns a spotlight on the role of Eurostars' participants and of ethics experts in the ethics review and also on the role of third countries.

Further to these studies, additional inputs from other work packages have provided substantial orientations for the present *Framework*. These were mainly collected in the context of the PRO-Ethics Pilots of Phase I and especially the cross-pilot learning workshop and IT tools workshops, as well as ongoing internal discussions among the fifteen European institutions and organisations involved in PRO-Ethics. The inputs from the work on testing the ethics framework in real-life Pilots (WP2) have **consolidated the fields of action covered by the Draft Framework**, namely the actions taken within projects, those undertaken in agency processes, and those carried out in evaluation processes. The feedback provided on **potential biases in the selection of participants** has also highlighted the need for an **emphasis on the design phase** of participatory practices, including the ethical risks to be anticipated, or further tackled at a later stage. These insights have helped to **consolidate the structure of the present Framework**, in addition to the knowledge provided by the first cross-pilot results on the implementation of the ethics framework and the related guidelines (WP3). This additional feedback confirmed the work undertaken in the RFO analysis of WP1, while it also **validated the need for a re-assessment of the added value** (expected benefits), the **need to define non-traditional actors**, as well as the presence of specific issues in the design process that could not allow for a universal one-size-fits-all setting. All these insights have been integrated into the first structure of the Draft Framework, which has been **discussed and validated by external stakeholders** during the WP4 Stakeholder engagement workshop. This workshop reflected on the general structure of the present Draft Framework and stressed the importance of having a common reference, while it also raised some questions on some specific features, thereby leading to a partial restructuring and a clarification of the context of use of the guidelines.

[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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Table below: Merging different activities (WPs) into the Draft Framework

Conceptual Framework (WP1)	**Testing the ethics framework in real-life Pilots (WP2)**	
▸ Need for guidelines as a common reference on ethics of participation ▸ Categories of participants and participatory activities ▸ General considerations on ethics and participatory activities ▸ Characteristics of current participatory practices ▸ Evaluation of the added value of participation	▸ Ethical risks and the stage of the project in which these risks may occur ▸ Potential biases in the selection of participants ▸ Fields of action (innovation projects; agency processes; evaluation processes)	***Draft Ethics Framework***
Cross-pilots learning (WP3)	**Stakeholder dialogue, reflection and embedding (WP4)**	
▸ Common trends in RFO processes ▸ Participation of non-traditional actors in R&I ▸ Expected benefits of participation ▸ Specific challenges in the design process ▸ Ethical challenges and issues critical to RFOs	▸ Validation and critical reflection of Framework ▸ Input for restructuring ▸ Clarification and reflection on context of use (identifying why and when engagement is valuable)	

Overall, this PRO-Ethics consortium feedback has highlighted: the need for precise definition of what participation and ethics actually mean; the need to identify which dimension of ethics we address; the potential differences among sectors and timelines (concept phase, project phase, after project phase); the need to better identify ethical risks and how to avoid them; the need for a checklist for what to consider when involving participants; the expectation of a thorough reflection about the ethical challenges, biases and points of attention. In addition to this, specific issues have been identified so far on conflicting interests, methods, and lack of knowledge during participatory processes, and in particular, the need for clear taxonomies of participation actors and activities.

All these previous findings in the PRO-Ethics project have been explored and merged into the main components of this draft Framework. The guidelines of this Framework, summarised in the diagram below, summarise the needs and goals of the Pilots, as well as the previous theoretical findings in PRO-Ethics, leading to this original and comprehensive structure.

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<table>
<tr><th colspan="4">Structure of the Framework</th></tr>
<tr><td rowspan="2">Type of participants: Which types of participants are targeted?</td><td rowspan="2">Type of activity: Which type of activity is targeted by the participatory process?</td><td>Design: How should a participatory process be generally structured?</td><td>Ethics issues and risks: Where are the ethics issues and risks?</td></tr>
<tr><td>Implementation: Has the implementation deviated from the design?</td><td>Critical factors: Are selection processes addressing all critical factors (including sectoral or local/national specificities)?</td></tr>
<tr><td colspan="2">Outcomes and added value: What are the outcomes and added value of the process?</td><td colspan="2">Indicators: What kind of indicators can help to measure the outcomes?</td></tr>
</table>

Figure above: The main components of the guidelines of the PRO-Ethics Framework

The objectives of this Framework

This *Ethics Framework* is the first version of the final main production of PRO-Ethics: as a key instrument, it is meant to be implemented and tested within the next PRO-Ethics activities (Pilots) before reaching its final, verified version. More than an internal tool, this *Framework* aims at a broad dissemination and adoption: it is meant to operate as a **roadmap** for all RFOs, providing some important ethical features that are not context specific. In that respect, the *Framework* is intended to cover all stages of participatory activities (design, implementation, feedback) applying to either design, development or output phases of R&I processes. It will also provide a list of questions and operational steps to consider for each ethical dimension; and will also provide some clarity both on the design and the implementation of participatory processes, as well as for social impact evaluation. Thanks to its format and scope, this Framework intends to respond to any specific context of implementation, providing a list of key topics and questions to be addressed in order to **determine whether an ethical participation process is possible, or necessary, and if so, how it should be structured in view of the different factors that should be integrated**.

This *Ethics Framework 0.1* is structured in two parts:

i) a general descriptive part (theoretical introduction) explaining the context of use, presenting the scope, the objectives and the framing of this *Ethics Framework 0.1* and how it is meant to be used;

ii) ii) a 2nd part, of operational nature, providing the tools and guidelines and also a general Glossary, which will present the main categories (taxonomies) and definitions (which are essential components of the *Ethics Framework*) and also broader definitions of frequently used terms. The second part — Tools & Recommendations — of this *Framework* has the format of a leaflet in order to be as directly operational as possible. Divided into separate sections, these recommendations and guidelines take the form of "actions" to be implemented, in a similar way to a checklist, addressing all main ethical considerations. As such, **this list of questions should be asked prior, during and after designing and implementing a participatory process**, thus aiming to cover the main ethical aspects — regardless of the specificities of each context — as a list of actions and verifications to be made that will ensure an ethical participatory process. This roadmap is meant to be understandable and meaningful for a broad audience, beyond Europe and beyond RFOs.

Defining a methodology of participation is a process that needs to take into account diverse perspectives and a combination of clear identification and matching of processes, actors and outcomes. This *Framework* will provide guidance both for innovation projects and innovation funding practices, thus addressing participatory R&I practices supported and implemented by regional and

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national RFOs. In terms of criteria and understanding, this *Ethics Framework* also takes into account the current discrepancies regarding the use of formalised/standard procedures on ethics of participation, as there is a lack of guidance or formalised procedures relating to ethics and participation in some national contexts. Citizen and (non-traditional) stakeholder participation can take many forms and a variety of subtle distinctions have to be embraced in order to **specify the exact conditions under which an individual or a group is or should be invited to participate, with what tools, knowledge, expectations, when, how, and with what outcomes and impact in decision making.**

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3 Part I: General Considerations

3.1 On Ethics

3.1.1 General considerations on ethics

Although some of the requirements to reach a high-quality level of participation can be covered by ethical compliance, the consideration of ethical grounds may result in ethical tensions (legitimacy conflicts between ethics and participation). Indeed, ethics can focus on the types of relationships between actors, but may also turn towards problems to solve, where a more professional ethical expertise is expected in order to produce complete ethical arguments or counterarguments with a technical knowledge of the problems to assess. Yet, the design of ethical processes addresses the issue of the right momentum, as ethical guidance could be ineffective once technology or R&I processes are already developed, thus urging for an anticipation of future consequences through ethical discussions when they can still be used to inform the R&I processes and decisions[6].

Considering the **complexity and unpredictability of innovation environments**, the concept of responsibility could be considered as a key dimension in R&I. This ethical stance also serves to prevent R&I processes that could be considered as "irresponsible", mainly occurring in contexts where the importance of the innovation's societal context has been miscalculated or when unresolved conflicts have taken place during the innovation process (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 co-production of solutions to global challenges and purposeful science, upstream engagement[7], and reflexive responsibility of scientists and innovators[8]. In this perspective, ethics cannot be reduced to formalised or standard procedures only, and their occasional confusion with the legalisation of ethics (soft law, ethical compliance) blurs the scope of their contribution. Also, ethics should not be considered as a toolkit but as a field (from applied ethics through to meta-ethics[9]) and a specific perspective that extends the regulatory schemes: **ethics helps to decipher the legitimacy, the tensions, and the adequacy of processes and legal compliance in regards with contextual criteria**.

The **pluralism of moral theories** suggests that — while deontologism (assessment based on universal principles and duties) may seem to be most relevant approach — there are several rational paths that can be followed through ethical pluralism in regard to ethics assessment (in justification context): types of entities assessed (i.e. action, person, institution, technology) from a normative ethics 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 indicate the need to move beyond regulations (as in ethics review/assessment), and to embrace a broader, pluralistic, scope. These views imply an enhancement of reflexivity and responsibility, this latter being polysemic and 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 ethical appraisal (assessment) procedures such as the ethics review, are not covering ethics but are rather closer to legal standards and regulations. The current ecosystem of publicly funded R&I has an advanced set of ethics assessment procedures, ensuring the compliance of funded research activities with fundamental ethical principles. However, the ethics review process differs across countries, since

[6] 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.

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

[8] 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.

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

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such formalised ethics procedures are usually systematically occurring in the context of funding programmes supported by the European Commission. The impact of the ethics review[10] has a different impact on projects depending on consortiums' structure, sector of innovation, and the involvement of non-EU countries. The current European landscape of regulatory bodies reveals gaps and difficulties in the merging of ethical practices with participatory practices in R&I. Overall, the study of resources across ethics regulatory bodies shows that the connection between ethical practices and participation is not yet developed enough, as the connection is often unspecified, maintained at the level of a general appreciation of potential benefits to keep a transparent relationship with society across R&I processes, mainly in regard to matters of public acceptance and public trust.

On a wider scale, the consideration and practice of ethics in R&I requires specific skills and knowledge that researchers, scientists or innovators usually do not have. Ethical analysis encompasses identifying ethical aspects of a project or issue (ethical questions or moral dilemmas at stake); familiarity and conformity with ethical standards; and ethical dilemmas when moral principles and specific methods to build, recognize and justify ethical issues are conflicting. The evaluation of right or wrong is based on ethical/moral values (ideals), or principles and norms that define standards – identified as "ethical principles" on a general level, some of them being principles concerning individual rights, principles concerning benefits and harms, fairness principles and virtues. By bringing a proper identification of ethical issues, ethics expertise provides guidance for R&I processes, a reflection on the consequences of the choices made, an enhancement of transparency (to a certain extent) and accountability, as well as a better quality of processes. In this respect, **ethical expertise provides tools to address the complexity and unpredictability of innovation environments, ensuring 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[11] is fundamentally of anticipatory nature 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"[12]. The diversity of cases highlights the importance of an assessment of the state of affairs in science and the type of uncertainties involved. Indeed, "uncertainty" can relate to several cases: in dealing with hypothetical effects and imaginary risks that require independent scientific evaluation, both transparent and publicly accessible; when facing a defined and quantified risk, which implies that policy makers can respond with a normal risk management approach; in situations in which one cannot fully rely on the scientific information system as such when it comes to the estimation of possible adverse effects requiring a precautionary approach; and when particular cause-effect relationships cannot be scientifically established, although adverse effects are known[13].

3.2. On Participation

3.2.1 General considerations on participatory practices

Participation is perhaps the most destabilising pillar within Responsible Research and Innovation (RRI) "keys", while the relationship between participation in R&I processes and ethics is complex. This is due to the diversity of ethical grounds supporting participation, which can vary according to the grounds on which participation is sought (normative/moral justifications) and that can either refer to ethics (ethical concerns, ethics broadly understood); to policy (ethics reviews, RRI); or to laws (regulations).

[10] 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.

[11] 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).

[12] 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.

[13] Von Schomberg, R. (2012). The Precautionary Principle: Its Use Within Hard and Soft Law. *European Journal of Risk Regulation, 3*(2), 151-152.

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The configuration of the involvement, the timescale, and the final outcomes of the processes can entail either strong or poor forms of participation. The legitimacy of participation is not self-evident and is often opposed by those who consider that scientific work is already exposed to many constraints both internally and externally (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]. Set as a priority by the European Commission, open innovation 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]. All forms of participation embedded in R&I processes rely on this premise of the unquestionable added value of any process of involving individual or collective actors not traditionally involved in such processes (referred to as "non-traditional stakeholders"). This assumption is based on the ideal of participative democracy, an overarching normative category encompassing different approaches, outcomes, activities and timelines[16]: this approach stems from a context of loss of public trust — a democratic deficit particularly salient in the current science-society relationship — where participation springs up as a remedy. Another assumption supporting participatory approaches is that complex public problems can be tackled efficiently by opening channels of participation inviting citizens and stakeholders in public decision-making[17], especially considering these voices can be at odds with expert and scientific positions.

Public concern over the impact of emerging technologies is an issue that is embedded in the grounds of participatory processes, with the underlying objective of allowing interested and — directly or indirectly — affected parties to take part in discussions about science, technology and any form of R&I processes. **Despite thirty years of participatory technology assessment in Europe, issues such as "why?", "how?" to participate and in order to reach "what quality?" are not yet solved**[18], which arguably weakens the legitimacy of participation. The first questions arising with participation in R&I processes are with what purpose, how, and consequently, when is participation occurring? Additionally, the question of the timeline should be considered, as each stage has a different array of implications, while some participatory activities (e.g. evaluation) can be also considered throughout the whole timeline.

The connection of participation with ethics has several layers of complexity: there are, for instance, several participatory (formalised) procedures; several goals; and several connections to responsibility[19]. Differences can be identified in the perspective they offer on ethics; the tools of governance used (ethics committee, participative or deliberative devices, etc.); the understanding of responsibility upon which the actions undertaken rely (often implicitly); and, finally, the characteristics of the inclusion process (e.g. participation or deliberation, the decision-making powers of the stakeholders involved). The legitimacy of participation can be broadly justified through different understandings of responsibility, which, in RRI literature, can be connected to process or outcomes, bearing a variety of meanings, both positive and negative ones.

Overall, there are many different goals for participatory practices, many different approaches to accomplish it, and many different ways to connect the outcomes of participation to decision-making. More specifically, there are many different ways to approach participation within the assessment of technologies, laws, research projects and policies, such as: citizen juries, consensus conferences, deliberative conferences, the Delphi and Charette methods, focus groups, planning committees,

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

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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, amongst others. The outcomes of participatory processes in terms of connection to decision-making are also diverse, since reaching an agreement could materialise under consensus, compromise or another form, including consent to disagreement, for instance. In technology assessment, ten goals of participatory practices can be outlined: assessment of consequences and technical options; extension of perspective for R&D policies; agenda setting; mapping of public scientific controversies; more interactive surveys; coverage of all arguments; reframing of the debate; mediation; policy recommendations (for new technological fields); comparison of new forms of governance.

Who participates is another key issue in the definition of participation, usually identified as "citizens" or "stakeholders", which are not overlapping terms, nor covering the whole array of potential participants. Commonly identified as an "inclusion" mechanism, participation can embrace various kinds of participants, including stakeholders, citizens, the general public (lay people), and civil society, in addition to usual participants (scientists and experts). Given the numerous ways to involve citizens or stakeholders in participatory processes for R&I, the questions of who is to be involved, by whom, when, and for what, imply also a clear identification of the publics.

PRO-Ethics intends to maintain a wide spectrum of participation actors across all dimensions of participatory processes. As a category, "citizens" is broader than "stakeholders" and can ultimately embrace all types of participants in their belonging to a given society. At the same time, "citizens" can also be seen as a category opposed to "stakeholders" as it implies an action towards the common good, ultimately raising the question of the societal purpose or implication of an R&I activity, while other categories can help to better frame the quality under which citizens are included in a participatory process (e.g. as end-users, or as part of the organised civil society). Who are the publics, either individuals or collectives that should be associated, in which capacity, how, when, and for which outcomes? Defending ethics in the governance of R&I requires to adequately address the perimeter of ethics and not to restrain it to regulatory processes.

Moreover, a lack of definition of the proper process may lead to poor forms of participatory practices. **As there is no single definition of participation, PRO-Ethics opens up the meanings of participation to embrace the whole array of practices.** Even though there is no single approach towards participative innovation processes, the clear distinction of activities, timelines, expected outcomes and types of participants can provide a common reference. In response to this need, **the use of a common taxonomy and common indicators presented in this *Ethics Framework* are part of the guidelines and are meant to be used as a common tool**. In this perspective, reaching a rich form of participatory processes requires clarifying some questions, such as which participants should be included or excluded, the nature of the decision-making method (e.g. majority, unanimity, veto right, to go as far as possible with argumentation and/or discussion) and the connection to decision-making. Richer forms of participatory processes are to be found in deliberative models, promoting the idea of public participation through iterative processes and fair representation ideals: deliberation is a form of participation where dialogue, engagement and justifications are developed to respond to essential democratic requisites, reflecting the theory of deliberative democracy. Deliberation entails the need of adapted approaches to increase the level of deliberation, the proper assessment of the tools and knowledge that is being shared.

Our research for PRO-Ethics has identified several needs facing research funding organisations (RFOs). These relate to the definitions of participation and ethics in R&I; the ethical dimensions and ethical issues (as well as their sectoral specificities and how they relate to projects' timeline); the ethical risks and their avoidance; the need for checklists specifying what to consider when involving participants; and the need for general indications regarding ethical challenges, bias, and points of attention. In addition to this, specific issues have been identified on conflicting interests, methods, and lack of knowledge. At a general level, the distinction of types of engagement actors is essential since citizens and stakeholders, often used interchangeably, are distinct categories, such as citizens as individuals or as part of the organised civil society. Following these considerations, participation should be framed through a case by case approach, asking the adequate questions and considering the different options in accordance with the context, although some basic requirements, such as

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informed consent could be set as a stable basis in a context of responsible innovation, understood as the conduct of responsive processes.

3.2.2 Characteristics of current participatory practices

All European RFOs share a common minimal treatment of ethical aspects. However, not all consider ethics as a primary component of their current participatory processes, owing to a variety of national specificities of structural and procedural nature, and different capacities and competencies[20]. While citizen participation is pursued as a high-priority objective in the discourses and goals of publicly funded R&I, RFOs do not all have the structural means to develop citizen participation activities. As citizen participation mostly occurs before and during R&I, the importance of developing participatory processes after R&I, including social impact assessment, is commonly perceived, although is challenging to do. The involvement of external stakeholders —in a particular project or policy — can potentially increase the conflicts of interest that RFOs have to cope with, and not all have the competencies required to address this issue. Indeed, the intricacies of stakeholders' interest have to be analysed, the specific type of actors within the broad category of "stakeholders" needs proper identification, and decisions must be made about who is selected to participate and how. Stakeholders could be defined as individuals, groups or organisations who can either affect or be affected by an organisation's activities (with a distinction between economic and non-economic stakeholders), while they also represent shared interests. The selection of participants remains a global dilemma, that, ultimately, refers to the very framing of the notion of inclusion and democratic representation in our societies.

The added value of participatory processes is another essential feature difficult to identify and that meets diverse views (from experts and participants, for instance), the legitimacy being the main guarantee of the sustainability of such processes, although legitimation can be considered at different levels (e.g. law, authority, competences) hence resulting in either broad considerations or specific views. Main characteristics that play an important role in the outcomes of participatory processes are the conditions and goals of genuine participation, in regards to decision-making; the means and needs of RFOs, the categorisation of modes of participation to outline the perimeter of "participation" in R&I; the ethical challenges and issues related to participatory approaches that are critical to RFOs (identification and representation of participants, avoidance of biases, use of personal data, etc.). All aforementioned conclusions from the critical review of legal, regulatory and institutional frameworks pertaining to the involvement of citizens and stakeholders, have been used to develop the specific recommendations and guidelines in this *Ethics Framework*.

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

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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. 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 ordinary citizens and 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.

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

A. How should a participatory process be designed?
B. Which type of activity is targeted by the participatory process?
C. Which types of participants are targeted?
D. Where are the ethics issues and risks?
E. Are selection processes addressing all critical factors?
F. Has the implementation deviated from the design?
G. What are the outcomes and the added value?

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 a participatory process be generally structured? *[before]* *[during]* *[after]*
▸ ***Action A1: Identify the expected type of contribution and the expected type of input.*** *[before]*
Identify why you are interested in certain types of knowledge and perspectives in the first place. This will allow for the design of more focused discussions and will ensure that the overall intention justifying the need for a participatory process is properly framed and outlined.
▸ ***Action A2: Allow for flexibility in the planning of the participatory process.*** *[before]* *[during]* *[after]*
All stages of R&I processes should be interconnected with the design of the participatory process, anticipating future impacts. Since unexpected nuances and concerns of participants may reveal themselves in the course of the project, flexibility is needed to be considered from the outset, in order to adjust and consider new findings openly. Participatory processes should therefore allocate enough time and resources for their final stages, in order to secure the uptake and incorporation of results and also to secure a meaningful impact. The allocation of resources, time and the selection of participatory methods[21] is intertwined with the extent of flexibility, which should be determined as accurately as possible.
▸ ***Action A3: Enable a feedback loop and dialogue between RFO and R&I projects; as well as between RFO/R&I projects and participants.*** *[before]* *[during]* *[after]*
Feedback from concrete experiences in specific fields can provide useful indicators to evaluate where the focus of participatory processes should be placed and how engagement should be furthered in future activities. Transparency towards participants should be established from the outset, by appropriate framing of the overall objectives, the nature and process of the involvement, the expected outcomes, the rights and boundaries of participants and the transparency and accountability commitment on behalf of the organisers of the participatory process. In this perspective, the design of the participatory process should encompass feedback mechanisms.
▸ ***Action A4: Consider the long-term impact of the R&I processes that are considered and the ways to design a participatory process that relates to this concern.*** *[before]*
This action should also address concerns of sustainability, of potential affected people/publics, and of long-term unforeseen consequences either of social, economic, environmental, cultural, political, or scientific nature. Any relevant long-term impact(s) that is/are expected should be listed and further related to the overall design of the participatory process.

[21] Regarding the diversity of participatory methods to choose from, please refer to section 3.2.1 (above).

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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 the above-mentioned framing of intent, possibilities, concerns and impacts, these features have to be associated with the identification of the proper participatory activities (see below), in terms of level and type of interaction that is expected, in view of the overall objectives sought.
On a general note, citizens and stakeholders can variously connect to R&I in terms of contribution and proximity — either internally or externally — to the R&I process[22].
Under this bipartite distinction, three categories of participatory activities are outlined:

- **Citizen and stakeholder engagement in innovation projects**
- **citizen and stakeholder engagement within agency's processes**
- **citizen and stakeholder engagement in evaluation processes**

Within these categories, several types of activities can be outlined, helping to separate the different outcomes of activities involving the participation of citizens:[23]

- **General consultation**
- **Evaluation** (of projects)
- **Information/knowledge sharing**
- **Monitoring**
- **Programme design**
- **Social impact evaluation**
- **Project execution**

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

- ***Action C1: Identify which actors / groups of actors to engage and why, connecting the methods with the context and the type of stakeholders to be involved. Then connect to the previous section (identification of participation activities), so as to cross-check the adequacy.*** *[before]*

The categorisation of participants is important both from the perspective of the general distinction of categories and also regarding their proximity with the R&I process[24]. 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. Indeed, the result of the R&I process may be external to the participants' condition (or involvement), or in other cases (e.g. human participants), the result of the R&I process directly affects them.
Following the level of participation that is targeted, the features outlined should be associated with the general identification of the adequate (groups of) participants, according to the nature of the R&I context and the type of participatory activity that is targeted[25].
This preliminary identification will ensure the methods that are considered to be applied are fully compatible with the context and the type of citizens or stakeholders intended to be involved[26].

- ***Action C2: Define how a person/group is involved, under what category and implications (ex. how to define a person's role as a citizen).***[27] *[before]*

[22] This distinction may have direct consequences in the way participants should be treated (e.g. in medical research on human participants, research on vulnerable people is often only allowed if they directly benefit from it).
[23] The definitions of this classification are to be found in the Glossary (last section of this *Framework*).
[24] See previous section (B), above.
[25] See above, section B.
[26] 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).

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Following the previous general identification, the actors / group(s) of actors should be further detailed, reaching the highest level of precision possible. To do so, the following taxonomy will serve to identify which category or categories might be associated and relevant in the given process:[28]

- **Citizens** (ordinary people defined as the general public, including citizen scientists and open science movements)
- **End-users/consumers**
- **Experts**
- **Private bodies representatives** (including institutions, organisations, firms, Innovators and entrepreneurs)
- **Public bodies representatives** (including governmental institutions)
- **Organised civil society representatives**
- **Research participants**
- **Scientists and research institutions representatives**

Activities		Participants
• **General consultation** • **Evaluation** (of projects/programmes) • **Information/knowledge sharing** • **Monitoring** • **Programme design** • **Social impact evaluation** • **Project execution**	⟷	• **Citizens** • **(End-)users/consumers** • **Experts** • **Private bodies representatives** • **Public bodies representatives** • **Organised civil society representatives** • **Research participants** • **Scientists and research institutions representatives**

D) Where are the ethics issues and risks? *[before]*

- ***Action D: Within each level and timeline phase of R&I processes, identify the ethical issues and potential R&I risks with an ethical dimension, and enhance structural means within RFOs, so as to be able to tackle them appropriately.*** *[before]*

Once the participatory activity and the participation actors have been defined[29], each of the following potential ethical issues and risks should be considered and further explored if relevant to the given context, in order to determine the feasibility or the participatory process or the need for adaptation. Advice from ethics experts should be sought in case any of these issues is deemed relevant.

Consider the following potential issues related to specific R&I processes:

- **In project proposals:** Regarding planned products, systems and services, and the people involved in projects, issues of human dignity, protection of privacy and data protection, transparency and gender biases should be considered.
  - Potential issues might be: informed consent (integration in/compatibility with the national context); anonymous submission; overrepresentation of certain groups; imbalances in the representation of citizens; insufficient knowledge on the scope of the project; tensions between the scientific quality and the potential benefits of a proposal (during assessment); adequacy and clearness in roles of the panel

[27] Some of the categories indicated below might partially overlap; in such case, please consider the prevailing category that would characterize a participant best.
[28] The definitions of this second classification are to be found in the Glossary (last section of this *Framework*).
[29] See section B and section C (respectively).

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members; use of panel involvement in the final project selection phase; communication and full information feedback to project leaders.

- **In project execution**: Issues relating to personal data; discrimination (including gender biases); stigmatisation; technology acceptance; dealing with vulnerable groups; distribution of control between humans and technology; privacy; safety; social responsibility of researchers; dealing with social roles in the application context; use of ethically sensitive findings; manipulation and guardianship through technology.
- **In evaluation processes:** Common ethical risks of legitimacy (due to the lack of formalised ethics review procedures) regarding members' selection, conflicts of interest (such issues are also occurring regardless of the involvement of citizens); ethical issues in the link to an ethics checklist that is included in the national call text; lack of ethical expertise (at least one evaluator should normally have expertise with respect to ethical issues); ethical issues in promoting the call by specifically addressing ethical issues in events.
- **In agency's processes:** Ethical issues might appear in the call text (programme design); in the planning of one-way engagement activities (information/knowledge sharing/communication) which, in their lowest forms, could be unduly considered as participatory; in the impact of participation, depending on the proper interpretation and understanding of the context in which it is conducted; in the degree of development of the ethical reflection and the ethical competencies.

Consider the following issues that may occur at general level:

- ***Conflicting interests:***
  - Ensure there are no conflicts of interest (conflicts with existing funding structures and processes; or internal conflicts related for instance to doubts regarding the planned participatory process);
  - Ensure that citizens and/or stakeholders' participation also includes a representation of diverse voices and voices at odds;
  - Identify potential issues of legal capacity (impartiality; partiality; external conflicts).
- ***Methods:***
  - Take into consideration that when participation is made a mandatory requirement for funded R&I 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;
  - In the case of top-down funding calls, reflect on the possibility of having a participatory topic identification;
  - Ensure the selection of participatory approaches are clearly answering the following questions: who? when? how? (see previous sections).
- ***Lack of knowledge / awareness:***
  - Since the option of participatory processes is sometimes not taken into account because of a lack of information (either at institutional or at citizens and stakeholders' level), a dissemination strategy and the identification of adequate resources to inform potential participants should be considered;
  - Identify the level of knowledge needed (scientific/technical background) for the execution and future evaluation of the participatory activity, in each specific context/sector considered; and ensure that potential ethical problems that have been spotted find the required expertise.
- ***Scientific integrity:***
  - Identify if (and how) the engagement might affect the researchers?
  - Ensure the methodology of participation and the reporting on the outcomes of participation are properly adapted to the values of Research Integrity;
  - Ensure the ability — at RFO level — to properly relate the participatory process with

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the scientific community and their values.

E) Are selection processes addressing all critical factors? *[before]*
▸ ***Action E: During the design of a participatory process, take into consideration the following sensitive factors and adapt them according to national contexts.*** *[before]*
Further to the ethical risks and issues[30], this action ensures that the criteria to implement fair and gender sensitive ethical procedures within new interaction modes are considered, so as: • To provide more opportunities and access to innovation for those who are excluded, which involves reflecting on the proper balance between pluralism and representation (proportionality): this may induce potential compromises to reach inclusion, as well as potential overrepresentation of minorities. • To properly determine when a category of people is included and who exactly is excluded; • Clarify the process of selection, the socio-demographic criteria used, the justification of the choice, and the categories of participants (referring to the above-mentioned list). **Selection of citizens and stakeholders:** ○ Reflect on the initial identification of participants[31] and the way they effectively relate to this assigned category, in case a change of category is needed; ○ For each category of participants (e.g. citizens or scientists) identify which knowledge background is expected from them and on which they will be asked to act upon; ○ Ensure there have not been biases in the selection of participants and that there is a broad representation; ○ Consider potential issues of asymmetric access to information on behalf of citizens and make sure such issues can be tackled; ○ Put in balance the potential benefits and challenges of different selection processes that you consider (diversity of participants, size of the group) and relate them to the project's objectives or subject; ○ Ensure the collection and processing of personal data is addressed, according to the applicable national and European legislation; ○ Ensure vulnerable groups are meaningfully involved/engaged; ○ Identify the right segment of stakeholders that should participate and the purpose of their participation for the right purpose and avoid the involvement of participants whose contribution is not properly identified; ○ In the case of topic selection, consider the level of participants'[32] expertise that might be required and make any necessary adjustments prior to the final design of the participatory process; ○ Identify all potential stakeholders in regard to the context, sector, project/programme needs, expected outcomes and representativity issues to include voices at odds; ○ Anticipate the potential clashes between certain types of participants, or between participants and the participatory methods to be used, and identify the methods to properly tackle and overcome them; ○ Consider whether a digital or analogue manner for involvement is more appropriate.

[30] See above section D.
[31] See above, section C.
[32] This relates to the expertise that is expected on behalf of participation actors (citizens or stakeholders — see above, section C, the related taxonomy) in view of their contribution to the participatory activity.

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F) Has the implementation deviated from the design? *[after]*
▸ ***Action F: After a R&I process that has included citizen or stakeholder participation, consider the following questions and criteria, and in case they are not met, modify future RFO participatory initiatives.*** *[after]*
• Participants of engagement activities should be first broadly identified, then categorised according to the taxonomies (question C, above) as well as the category of activity and the level of action (question B, above), trying to reach the highest level of detail both in regard to participants and to activities and to identify any potential deviation during implementation from the initial design[33]; • Depending on the outcomes of the participatory process, while some inputs may be chosen to be disregarded, the overall accountability process should consider all voices and keep track of those excluded from the final outputs; • Verify if representation and inclusion of participants have been addressed throughout the whole timeline of the R&I process, in order to identify potential deviations in the adequacy of their selection or in their treatment; • Ensure that the actual input from citizens & stakeholders is taken into consideration in the final decisions following a participatory process; • The societal justification of participation should be taken into account as it ensures that the quality and functionality of procedures connects with societal needs.

G) What are the outcomes and the added value? *[before]* *[during]* *[after]*
▸ ***Action G1: Before and during implementation of the participatory process, consider the additional resources needed for participatory approaches, which need to be balanced against the expected benefits.*** *[before]* *[during]*
Participatory processes should be accompanied by sufficient resources to ensure beneficial outcomes. Moreover, the added value of a participatory process is partly determined by the balance between the expected benefits and the costs and resources effectively dedicated to the participatory process. This balance should be determined as precisely as possible from the design stages of the participatory process. This should be addressed both before the implementation and during implementation of the participatory process. The added value should also relate to the specificities of the contribution of the selected participants (e.g. citizens) and the reasons why the chosen category has provided a contribution that could not have been provided by other types of participants.
▸ ***Action G2: Before and during implementation, and on the basis of the previous action, establish a timeline for the monitoring of participation outcomes.*** *[before]* *[during]*
This reflection should mention which outcomes are expected to be kept and integrated into R&I/RFO processes; ii) which outcomes are not expected to be kept (and the reason why). During implementation, these expectations should be reconsidered and adapted if needed, following a reflection on the deviation from pre-set indicators in the tangible results of the participatory process[34].

[33] This distinction has an impact on the overall participatory approach: see indications in sections B and C.
[34] This action is complementary with A2 and A3 (see above, section A).

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▸ ***Action G3: After the completion of the integration of participation outcomes, launch a transparency process allowing participants to interact.*** *[after]*
According to the size of the participatory activity and the organisational capabilities, participants may be contacted to receive information on the treatment of their participation (e.g. data protection), the specific features that have been kept or rejected, the overall objectives met through the outcomes of the participatory process and allow them to interact. This feedback from participants should be collected as a main source of assessment on the process and should be considered in future stages of participatory processes, indicating potential needs for adaptation. An ideal implementation of this action would be to officially acknowledge the right of citizens (or stakeholders) to assess the outcomes of their proposals/inputs and to request accountability provisions.
▸ ***Action G4: Establish a form of compensation/acknowledgement of the participants' contribution.*** *[after]*
The result of this action should ensure participants feel their contribution has been considered and valued. This could consist of a financial retribution or an official acknowledgement, according to the possibilities in each specific context.
▸ ***Action G5: Establish a list of benefits from the participatory process that could not have been achieved without the involvement of the specific participant(s) or group(s) of participants.*** *[after]*
This action serves to verify the assumption that participation is justified in all cases, regardless of the reasons and approaches.
▸ ***Action G6: Both in view of future reference and for accountability matters, all reflections answering the actions mentioned in these Guidelines should be kept in a synthetic report, to be archived by the RFO and reviewed by its Board members at later stage.*** *[after]*
Keeping track of all aforementioned actions related to the participatory processes will enable appropriate treatment of transparency and accountability issues that may arise at a later stage, and also should serve for any future retrospective analysis of the process(es) undertaken.

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H) Glossary

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

- how a person/group is involved, under what category and implications;
- the type and level of activity of participatory processes;
- general terms of interest;
- distinct levels of interactivity/degrees of involvement of society in research.

The categories and definitions outlined below reflect the work undertaken in PRO-Ethics and serve as common references. **Some of these categories are part of the "classifications" in the above sections of the Tools & Recommendations** of the present *Ethics Framework*; others are additional terms and definitions of usual concepts and notions that are commonly used to describe ethics and participation within R&I processes.

Citizens

This category includes the general public, lay people, and citizens as persons (or collectives) with civic expectations[35]. 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).[36]

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.[37]

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

[35] In this category, the main boundaries for the "citizens" category are anchored in the citizens/stakeholders distinction.
[36] Source: https://www.invo.org.uk
[37] 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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interim and ex-post evaluation for projects and programmes that received funding; and programme evaluation.

Experts

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).

Funding budget

Most RFOs distinguish between "commitments" e.g. allowances for new projects and "liquidations" e.g. payments for current projects. In the context of PRO-Ethics, we always refer to the commitment budget.

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.[38]

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.[39]

[38] Source: https://www.invo.org.uk/
[39] Source: PRO-Ethics D5.1

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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).[40]

Private bodies representatives (innovators/entrepreneurs)

Representatives of small and medium-sized enterprises (SMEs) or large companies (including those conducting research), considered as beneficiaries (actors who implement the funded proposals) or non-beneficiaries of funding schemes and involved in some way in RFO activities as participants, participating on behalf of their company. This category also comprises social entrepreneurs.

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.

Project lead

The project lead may be a principal investigator (PI) or a coordinating person/institution/enterprise responsible for the whole R&I project.

Public bodies representatives (governmental institutions)

Also understood as governmental institutions, this category encompasses national public bodies (e.g. government department or ministry, excluding academic research institutions) that might be involved in the management of RFO activities and projects or that might operate as funding agencies. Public bodies relate to ethics through ethical compliance mainly, ensuring ethics requirements are met in grant agreements signed with the beneficiaries at a national level.

R&I (or RDI) agents

Research and Innovation (or Research Development and Innovation) agents include researchers in Higher Education Institutions (HEIs) and research performing organisations, as well as researchers, developers and innovators in enterprises, NGOs and public bodies. As in the case of "participants", "RDI agents" might be individuals (e.g. individual researchers) or institutions/institutional delegates (e.g. universities or firms) carrying out the research as beneficiaries.[41]

Research participants

This category refers to human participants that are part of the subject of research (for instance in medical sciences: public and patients' involvement).

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

[40] Source: https://www.invo.org.uk/
[41] Source: PRO-Ethics D5.1

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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".[42]

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.[43]

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

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