



ERA4Health Responsible Research and Innovation (RRI) Guidelines



Co-funded by
the European Union

Versions

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Endorsed by ERA4Health partners on: 31/10/2023

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These guidelines (i) introduce the idea of Responsible Research & Innovation (RRI), (ii) explain how ERA4Health approaches and supports RRI, (iii) offer practical advice for operationalising RRI in projects and how it can be evaluated and (iv) provide sources of further information for applicants.

ERA4Health hopes this document will also help you to prepare proposals to other health science programmes that include RRI-related aspects, for instance Horizon Europe.

This is a 'live document' developed by ERA4Health's RRI work package and RRI advisors (Ellen-Marie Forsberg, NORSUS and Robert Smith, University of Edinburgh) in conversation with health scientists and all R&I funding organisations from the ERA4Health community. Questions can be directed to ERA4Health's RRI lead Cecilie A. Mathiesen (cam@rcn.no).

ERA4Health has been funded by the European Union under the Horizon Europe Framework Programme. Grant Agreement N°: 101095426.

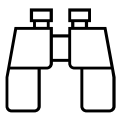
WHAT IS RRI AND WHY DO WE NEED IT?

Health research and innovation is crucial for maintaining and improving European public health. In this context, it is easy to acknowledge that science is not separate from society but part of it, which confers an important social responsibility on science. It is important, therefore, that funders, researchers and other key groups involved in the development of science, technology and innovation think about: (i) the potential directions of research being taken; (ii) who might benefit from new research and inventions and who might not; and (iii) how consideration of the potential social, environmental and ethical issues can be considered throughout the science and innovation process. Responsible research and innovation (RRI) is not about adjudicating what is 'good' or 'bad', 'positive' or 'negative', or 'responsible' or 'irresponsible'. Instead, RRI offers techniques, tools and frameworks to think about questions of social responsibility and ensure scientists, funders and technologists don't lose sight of the context in which they do science, technology and innovation.

RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/user engagement, open science or ethical assessments.

WHAT IS ERA4HEALTH'S APPROACH TO RRI?

ERA4Health's approach to RRI is focused on improving the quality of research and innovation by keeping the broader context of your work visible. It encourages you to embed methodologies and processes to consider four important dimensions related to research and innovation:



Anticipation. What might the future desirable and undesirable effects of your work be? Who will benefit from it, and who might not? Can decisions be made now to encourage the good, while minimising the bad effects? This isn't about exhaustive prediction but about building a sense of preparedness for the future.



Inclusion. Whose voices and knowledge are shaping your research project? In health research, much evidence shows that patient organisations, health care users and health professionals (amongst others) can improve the quality of innovation. Inclusion is about creating opportunities for two-way exchange of information, co-design or knowledge co-production to draw important outside voices into the research process.



Reflection. Are there opportunities for you and your team to pause and ‘take stock’ about what you’re doing? Would everyone agree with your goals and the decisions you’ve taken so far? Reflection is about making sure there is space and time to collectively ask hard questions about a project’s foundations.



Responsiveness. What are the key decision points in your project? Are there opportunities to change course, if you need to? The final dimension is a reminder that the work you do under the label of RRI needs to shape the design, governance or use of your research or innovation.

In sum RRI provides a framework to ask how research and innovation should be carried out in order to ensure that we achieve the societal goals of research and innovation in an open and inclusive way. ERA4Health believes that the RRI methodology improves the quality of research proposals and projects, and substantively engaging with this framework will therefore be rewarded in the proposal evaluation process.

HOW SHOULD YOU INCLUDE RRI IN YOUR PROJECT?

Experience with past funding programmes shows that these four dimensions – anticipation, inclusion, reflection and responsiveness – provide a useful heuristic to think about social responsibility across a range of domains. However, the diversity of health science and the range of local contexts engaged within ERA4Health means that there cannot be a one size fits all approach. The specific approach to RRI must be tailored to the actual social, environmental and ethical issues raised by a project’s research and innovation activities.

This means that **the commitment** to RRI is clear and fixed in the programme, but there is an openness about the issues addressed and the specific ways to practise responsibility – these must be adapted to each project. In general, your approach to RRI should be proportionate to

your proposal – disruptive, ground-breaking or high-TRL (Technology Readiness Level) work is likely to require a more substantive engagement with RRI. If the research is exploratory then RRI components can also be exploratory – teasing out the potential visions, goals and end uses of a project. Overall, the goal is to demonstrate that you have engaged and seriously considered the tensions and meaningful societal benefits associated with health research and innovation.

The text below therefore provides overall ideas and advice but cannot give a recipe that all potential applicants may use. However, the following four points will provide a good foundation as to how develop your approach to RRI in your proposal:

1. Treat **RRI as an integrated part of the project** involving as many project members as possible. Do not think of RRI as distinct from the science but as central to it. It is a process that will increase the likelihood of delivering applications with real utility, fair accessibility and concrete value for citizens.
2. It is important to develop a **shared understanding of the project's RRI aspects** as early as possible, and for the work plan to be specific to the project. Avoid writing generic, boiler-plate text. By 'RRI aspects' we mean implications or characteristics of your research that touch upon societal, ethical and environmental values.
3. **Develop the scientific and RRI components in tandem.** This means you will need to have conversations about the goals, uncertainties and assumptions associated with the scientific ideas. It is important to continue these conversations if the project is funded.
4. **Make sure you adequately resource RRI.** It takes time, effort, expertise and money to do RRI well. While there is no one approach to operationalising RRI within a project, ideally RRI needs to be coordinated and should have a lead.

BUT WHAT SHOULD YOU ACTUALLY DO?

Starting points to help you identify the most relevant dimensions for your project.

The following questions will direct you to different RRI perspectives applicable for health research and innovation projects. Many of these perspectives can be explored in a structured way with a range of methodologies (for additional resources, see box below). **Please be aware that these options neither represent a complete list of examples, nor the mandated approaches to RRI by ERA4Health.**

1. **Who will benefit from your project**, who will not, and who may experience new risks? Are those answers acceptable to you?
 - a. Does your project address a specific health-related or societal problem or need?
 - b. Will your innovation be affordable and accessible? If not, is that a problem?
 - c. Does your framing of the problem fit with other people's understanding of it? Can you access these alternative framings?
 - d. How does your approach to the health challenge compare to others approaches?
 - e. What is the most appropriate form of intellectual property (IP) for your project goals and affordability aspirations? Do classical IP strategies deliver the broadest benefit? Can new strategies (e.g. Open Material Transfer Agreements) be adopted at certain points of the research process?
 - f. How could commercial or non-commercial organisations benefit from your research?
 - g. Are there foreseeable risks that you can mitigate now? For instance, what are the potential risks of data being released? How can you take care to ensure these data are interpreted appropriately?

2. Have you identified and involved **relevant stakeholders and have you considered public engagement activities?** Are there opportunities for stakeholders and the public to contribute to your work? Stakeholders are people or organisations with a vested interest in the project (both positive and negative), who may also contribute knowledge to it. They could be patients, minorities and marginalised groups, health system users, special interest groups, health professionals, companies, nonprofits, or advocacy organisations. A number of different considerations for stakeholder engagement are important:
 - a. **Think about the methodology you will use.** For instance, 'co-design' and 'knowledge co-production' methodologies are good at generating trust and

allowing stakeholders, including the public, to contribute their knowledge to the problem your project is trying to address.

- b. **Think also about the appropriate timing** of different stakeholders' inclusion: certain kinds of knowledge may be more useful early on, whereas other knowledge may be useful later.
- c. It will likely be valuable (but not obligatory) to **include expertise beyond the medical and health sciences** – such as lawyers, social scientists or philosophers – to provide anticipatory and reflective methodologies or to address key challenges. Approach them early in your project design.
- d. Think about **how best to formalise and include stakeholder knowledge** in your project. Are they best placed as scientific collaborators, as members of an advisory board, or as consultants to deliver only specific tasks? Check if your approach is in line with the national/regional funding rules before designing your proposal.

3. Have you created good deliberative spaces for your project team, partners and aforementioned stakeholders, including the public, to anticipate and reflect on the broader social, political, ethical or environmental context of your research? If not, RRI experts in Science and Technology Studies, medical sociology, bioethics and science communication may be able to help you with this in project design and implementation. A number of different approaches are possible, e.g.:

- a. Focusing on your day-to-day research work (“philosopher in the lab approach”).
- b. Using foresight and critical futures methodologies.
- c. Utilising a diverse advisory board.
- d. Trans-disciplinary reflection at consortium meetings.
- e. Using stage-gate approaches where explicit decisions about technological choices are taken.

4. Have you reflected on/considered adapting your choice of research methods regarding, for example:

- a. Ethical issues in the project (including ethical considerations in the design of participatory science and possibly broader than the “ethics self-assessment”)?
- b. The use of data in your project – where does it come from, how will it be used and where will it go? How will ethical use be ensured?

- c. In vivo/in vitro experiments and need for use of animals in experiments?
 - d. Use of new approaches such as “Safe(r) by Design”?
 - e. Your ability to increase the likelihood of translation by outlining e.g. strategies of scientific rigour, and strategies to reduce bias, inclusion of sex/gender as a biological variable in study design?
 - f. Open Science (such as open data, open code, open protocol or other low barrier data sharing practices) and other publication practices (including report all results, also negative or so-called null results)?
 - g. And are there ways that your project can advance common practices on these issues?
5. Have you engaged with important aspects of **your research environment** such as:
- a. gender, ethnicity and intersectional equality, diversity and inclusivity?
 - b. career progression and precarity?
 - c. equity between partners in your research consortium?
6. Have you shown how the project (and product) satisfy requirements for **patient and production safety** and efficiency? Will there be clear benefits for the patient by, for example by:
- a. listening to/satisfying user needs and safety concerns, or involving them in design;
 - b. involving regulatory affairs professionals (toxicity tests, etc.),
 - c. communicating with regulatory entities as early as possible (the Food and Drug Administration (FDA) or the European Medicines Agency (pharmaceuticals and medical devices), etc.
7. Have you considered and evaluated **environmental impacts and sustainable solutions**, in line with the **Do No Significant Harm principle**¹, by including, for example:
- a. lifecycle analysis (LCA)?
 - b. ecotoxicology studies?
 - c. safer- sustainable-, or recyclable-by-design methodologies?

¹ For more information on this principle see point 15 in Horizon Europe’s Programme Guide, page 39:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

HOW DOES ERA4HEALTH SUPPORT AND EVALUATE RRI?

Health research and innovation happens in many different locations (e.g. universities, hospitals, care homes, companies, policy organisations), involves different stages of research (i.e. across the TRL spectrum) and different research cultures. Responsibility for innovation must be shared, and RRI therefore requires a multi-level approach.

ERA4Health is taking a systemic approach to RRI, considering it in the development of the annual work programme and the resulting funding calls. These guidelines were developed in collaboration with members of the ERA4Health community, and will be updated on a rolling basis. The programme's capacity building activities will also facilitate a dialogue among stakeholders in health research about RRI and ethical issues.

At the level of research projects, ***ERA4Health requires that all proposers explain how their projects demonstrate a commitment to investigating and addressing the social, environmental, ethical, political or cultural dimensions of the proposed research.*** Integration of RRI should lead to an improved understanding and awareness of the possible benefits, risks, and uncertainties of health science across a broad cross-section of society. This may include (but is not limited to) any of the approaches described in the above section.

In the (pre-)proposal templates, three sections/points refer to RRI and ethics considerations and leave space for you to explain your approaches:

- General RRI aspects
- Involvement of stakeholders and the public
- Ethical considerations (in your ethics self-assessment)

RRI components will be given advise on/evaluated by experts as integral components within the scope of all evaluation criteria (Excellence, Impact, and Implementation). RRI does not detract from the overall scoring but contributes to it: Proposals that explicitly aim to advance processes of anticipation, reflection, inclusion and responsiveness by developing new analyses or methodologies will be rewarded in the review process and the scores will be adjusted accordingly. In pre-proposals: The research consortia will receive advice on the RRI dimension from their proposal via written comments from an RRI Adviser that will be shared with the reviewers. In full proposals: RRI Advisers will comment on proposals before the Per Review Panel (PRP) meeting and be invited to give additional advice on RRI and support the discussions

during the PRP meeting.

The kinds of questions the RRI Advisers/reviewers will ask regarding RRI are:

Relating to *Excellence*

- Is the RRI approach proportionate to the content of the scientific proposal?
- Does RRI extend across the lifespan of the project? (e.g. as a sub-project, an advisory board or to be considered in annual meetings)
- Are there clear deliverables associated with the RRI work, with ambitions to contribute to RRI scholarship and/or new knowledge of the social, political, ethical or environmental dimensions of health science?

Relating to *Impact*

- Are there clear opportunities for the RRI work to shape the project's scientific trajectories?
- Does the RRI work help align the project's research better to the needs and values of society?

Relating to *Implementation*

- Is there appropriate RRI expertise in the project?
- Is RRI work adequately resourced? Is it clear *how* the objectives will be achieved?
- Is it clear how the work is organised? (e.g. as a work package, a cross-cutting issue, outsourced etc.)
- Is it clear who is doing the work and what they will do?

WEB RESOURCES FOR INCLUDING RRI IN YOUR PROJECT:

www.rri-tools.eu provide numerous resources for practical RRI.

<https://thinkingtool.eu/>: The Societal Readiness Thinking Tool guides you through the steps of including RRI in a project.

The Centre for Digital Life Norway [has also compiled a range of resources](#) that may help develop your approach.

Tools for public engagement: <https://www.publicengagement.ac.uk/resources> and <http://actioncatalogue.eu/>

Further examples specific to health science and innovation will in the future be provided on the RRI webpage of ERA4Health (coming).

ERA4HEALTH's approach to RRI builds on previous frameworks published by the UK's [Responsible Innovation-UKRI](#), the Research Council of Norway, the [European Commission](#) and funding programmes such as [M-ERA.NET3](#), [ERA CoBioTech](#) and [EuroNanoMed3](#).