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Innovative Genomics Institute

KEYSTONE POLICY CENTER

GENE EDITING & SOCIETAL ENGAGEMENT TOOLKIT:
RESOURCES FOR GETTING STARTED

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ABOUT THIS TOOLKIT

This toolkit provides guiding questions, planning frameworks and resources, and references to support gene editing researchers, developers and partners in getting started on societal engagement for gene editing. The toolkit was developed by the Innovative Genomics Institute, the Kavli Center for Ethics, Science, and the Public, and Keystone Policy Center.

WHY SOCIETAL ENGAGEMENT FOR GENE EDITING?

Gene editing has the potential to address urgent challenges in the environment, climate resilience, human health and food and nutrition security. Many diverse sectors and stakeholders share a mutual belief in the potential for gene-editing to deliver societal benefits while recognizing the important role of societal interests and social license in addressing concerns and achieving benefits.

Effective societal engagement on gene-edited products can:

- Guide work toward mutually beneficial outcomes
- Build trust
- Inform exploration of how problems are 'framed' and which solutions - gene editing and/or otherwise - might best meet societal needs
- Ensure that appropriate and culturally competent engagement, collaboration, and self-determination principles are upheld
- Support prioritization of which applications of gene editing to pursue and how to pursue them
- Support exploration of risks and benefits of specific gene edited products associated with a broad range of environmental, social, economic and cultural interests
- Increase inclusivity of decision making and governance on emerging technology
- Increase understanding of diverse views of stakeholders, communities, and the general public and how these views affect societal support for specific gene edited products
- Integrate societal values along with technical value to address complex issues that cannot be addressed by science alone
- Invite various forms of expertise and knowledge into co-creating goals and solutions
- Increase the capacity of partners - including historically underrepresented partners - to participate in research
- Increase transparency and accessibility of information about gene editing research
- Complement science-based regulation, industry transparency, and voluntary stewardship
- Create and sustain durable relationships, partnerships and collaborations across diverse perspectives that can result in reduction of risks and enhancement of societal benefits

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KEY QUESTIONS TO GUIDE ENGAGEMENT

There has been much dialogue about the importance of societal engagement for gene editing. The good news is that there are examples and learning to build from in gene editing and other fields. To move from discussion to action, start with the following key questions.

THE BASICS

There are basic questions and considerations that should guide any societal engagement effort. Check out these questions below. The design - including the scale, scope, mechanisms and duration/iteration - of engagement can differ significantly depending on the answers to these questions.

To dive deeper, check out the Collaborative Action Toolkit - Keystone Policy Center for a step-by-step process of inquiry that guides you through these questions to help determine the right level and form of engagement for your needs.

WHY? Why are you seeking to engage?
- What's your objective and the problem you are trying to solve?
- What are your goals?
- Are you looking to inform? To be informed? To collaborate? To empower others to make decisions?
- Does engagement have the potential to change your decisions? Which decisions? What constraints do you have?
- How much value does your organization place on engagement? Are you willing to hear and incorporate critical feedback? Will you move forward with your plans regardless?
- What are the benefits of engagement?
    - What would happen if you did nothing/did not engage? What might be the potential business and societal costs of failing to earn social acceptance?
    - Why might others want (or not want) to participate in your engagement?
    - What incentives or benefits do individuals or groups need in order to participate?
    - What might they expect to get out of participation, whether immediately or over the longer-term?
    - What relationships and influence might they build through participation?
    - How can they expect their input to be used?

WHEN? When should engagement occur?
- When will engagement of other perspectives be most impactful to your decisions?
- What are the benefits and tradeoffs of engagement at different phases of your decision process, for example:
    - Early scoping for information and frame issues and problems, when there may be a wider decision-making space, but less information may be available for participants' response
    - Later engagement for responses to draft plans, when the options or 'decision space' are clearer but also potentially narrower
    - Iterative engagement at multiple phases of a decision process

WHO? Who will be involved in engagement?
- Who within your team or organization will be involved in engagement? What diversity of perspectives and skills do they bring? What license do they have internally to respond substantially to external feedback?
- Who from outside your organization will support the engagement? Would you benefit from a third party process expert to facilitate the exchange?
- Who are the stakeholders, community members, and/or publics that you will engage?
  - Who is most impacted by the potential decisions you are making?
  - Who brings additional expertise, perspectives, authority, etc.?
  - Whose views have been previously underrepresented in your decisions?
  - Who is willing and able to engage? What supports are needed to enable them to engage?

WHAT/HOW? What is your engagement plan and how will engagement be conducted?
- How will you reach out to participants and invite them to the table?
- What culturally relevant practices, protocols, and rules need to be followed? What other cross-cultural considerations and sensibilities will you embed into your efforts?
- What modes of engagement?
  - What are the preferred modes of engagement of those participating?
  - What is most 'fit for purpose' for this effort?
  - How might the following be incorporated: Networks, listening sessions, joint fact finding, advisory groups, partnership, coalitions/dialogues? Group meetings vs. individual interviews and conversations; one time engagement vs. multiple sessions; in person vs. online?
- What information will you provide and what questions will you ask? How will information be provided in an accessible manner?
- What kinds of structures will uphold a respectful conversation? What guidelines, charters, agreements, etc. need to be in place?
- Will you/how will you allow participants to inform and/or co-create the process or the product? How can you use the process to build capacity for those that you are engaging or partnering with?
- What financial, human, and other resources do you need/have to conduct the engagement and build the relationships that are important to success?

FOLLOW-UP? How will you demonstrate how the engagement affected decisions?
- How will you bring information back to your internal organization and incorporate it into decisions?
- How will you assess the impacts, successes, and learnings from engagement?
- What's the plan for reporting back findings and results to participants on how their feedback was used?
- How will access and benefit-sharing be addressed as a result of participation, in recognition of the value of contributions of capacity, knowledge, and expertise?

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SPECIFIC CONSIDERATIONS FOR GENE EDITING AND SOCIETAL ENGAGEMENT

Beyond the basics, here are some questions to consider specifically for gene editing that may affect why, when, who, and how to engage.

PROBLEM FRAMING

- **Where are you in your product development cycle?** Are you scoping out what problems to work on? Looking for input to prioritize what research and development you pursue? Have you chosen a problem and a species to edit? Have you already developed a product? Where you are in the timeline affects your decision space, the influence engagement can have, and the questions that might be asked.

- **What problem are you trying to solve?** Climate resilience? Disease resistance? Nutrition? How does gene editing fit into the problem overall, and what role can it play in addressing the problem? What are the other alternatives to solving the problem? How does the problem that you're trying to solve affect who you might need to engage?

- **Product developer and past engagement.** Are you a private sector company? A public sector research institution? A nonprofit? What's your overall mission, and how does this effort fit in? How might this identity affect your stakeholders and networks, and levels of trust? How might your existing and past relationships or engagements affect this new engagement?

- **How does this specific product fit into broader societal dialogue on gene editing?** Are the biggest questions you have for this engagement about this specific product, or are they more general? How does this affect the role of the individual product developer and the potential to partner with other researchers and developers in broader dialogue?

WHAT ARE YOU EDITING?

- **What organism are you thinking about editing?** A plant? An animal? A microbe? How might this affect general engagement context and strategies?

- **What kind of edit(s) are you thinking about?** Are they relatively 'simple,' non-transgenic edits? Is it a single edit or multiple? Is it transgenic or GMO? Is it a gene drive? How does this affect the regulatory and societal considerations for this product?

- **Source of varietal being edited.** Is the organism/varietal that is being edited a commonly used/consumed species? Is it a species or varietal with cultural significance, sovereignty, and/or access and benefit considerations for historically marginalized and/or Indigenous communities?

- **Source of edits being introduced.** Do the new traits being introduced already exist somewhere in nature in this species? Do they exist in the region where the new product will be produced or introduced? Are they designed to mimic traits in other, non-related species? Are they being identified and/or sourced from a species or varietal with cultural significance, sovereignty, and/or access and benefit considerations for historically marginalized and/or Indigenous communities?

ADDITIONAL SOCIAL, CULTURAL AND ENVIRONMENTAL CONTEXT

- **Where is this organism grown, produced, or living in the natural environment?** What are the geography, climate, culture, demographics, and socioeconomic considerations? How does this affect who you need to engage and the factors affecting whether/how you develop this product?
- **Who is the target audience or consumers for this product?** What are the cultures, demographics, and socioeconomic considerations? How does this affect who you need to engage and whether/ how you develop this product?
- **What is the cultural relevance of the product?** Is this a dietary staple? A traditionally important species or food? Are there cultural and/or sovereignty considerations associated with its production and/or use in Indigenous cultures? Are there elements of the crop other than the edited trait in question that may affect receptivity? For example, is color, size, or texture of a food important culturally?
- **Environmental considerations.** Will this organism be grown only in a controlled environment? Will it be intentionally released into the wild? What are the considerations for gene flow from a controlled to a natural environment? What are the potential environmental risks (i.e., deforestation) and benefits (i.e., restoration? Pesticide reduction? Reduced water use or GHG emissions) of this product?
- **Public health considerations.** How might this product affect nutrition or food security? Pesticide exposure? Pathogen and disease flow among other species and humans?

REGULATORY, LEGAL AND TRADE CONTEXT

- **What additional regulatory considerations exist?** How does the country of production and/or consumption/use affect the regulation for this product? Are the relevant regulatory system(s) likely to approve this product? Are they set up well to handle this type of edit or product, or is this a novel test case? What societal engagement do they require, and how does the regulatory process affect other forms of engagement?
- **What transparency and market considerations exist?** Will this product be subject to labeling requirements, such as for products containing genetically engineered DNA? Does it have origin-based labeling requirements? Will the product be listed on product registries?
- **Intellectual property context.** Who owns the editing technology? Is the genome of the organism publicly available? Are there special licensing agreements that are needed? How will IP for the edited product be shared or protected? Have you considered technology access in the context of other institutions and communities that you might be working with to create this product? Could the IP landscape hinder or help in engaging certain communities? Could it serve as a mechanism for benefit sharing?
- **Context of other available products or options, markets, and trade.** Are there other, non-gene edited products that could provide a viable alternative to using gene editing? How will co-existence of gene edited and unedited products occur in the marketplace? How might this affect trade and exports?

ABOUT THE SCIENCE

Engaging on gene editing means connecting technical and scientific conversations with societal values, priorities and perspectives. Below are some basic resources about gene editing and CRISPR that can be helpful in providing background explanations to non-technical audiences in order to help enable full participation.

WHAT IS GENE EDITING?

Techniques to alter the DNA of an organism (genetic engineering) have existed for decades, and scientists have used these techniques to understand the living world and make advances aimed at improving our quality of life. While past methods for genetic engineering have relied on the ability to introduce or add genes into a genome, gene editing can be used to make additions, deletions, or substitutions of almost any DNA sequence within a cell or organism, and to do so with more precision and reliability than ever before.

Although many gene editing tools exist, such as [TALENs](#), [ZFNs](#), and meganucleases, CRISPR is the most commonly used and most versatile among them. Gene editing with any tool, including CRISPR, typically works by precisely targeting and cutting a selected DNA sequence. This cut is then repaired by a cell's natural repair mechanisms, enabling the introduction of new DNA content into the cut site or the disruption of the DNA sequence at the target site.

Gene editing represents a new biotechnological paradigm that is distinct from genetic modification or genetically-modified organisms ([GMOs](#)). Briefly, GMOs are organisms that contain introduced genetic material, sometimes from another species, that confer a desired trait or functionality. Gene editing, by contrast, expands the possibilities beyond gene addition, to enable changes that are otherwise indistinguishable from those occurring naturally or through traditional breeding.

WHAT IS CRISPR?

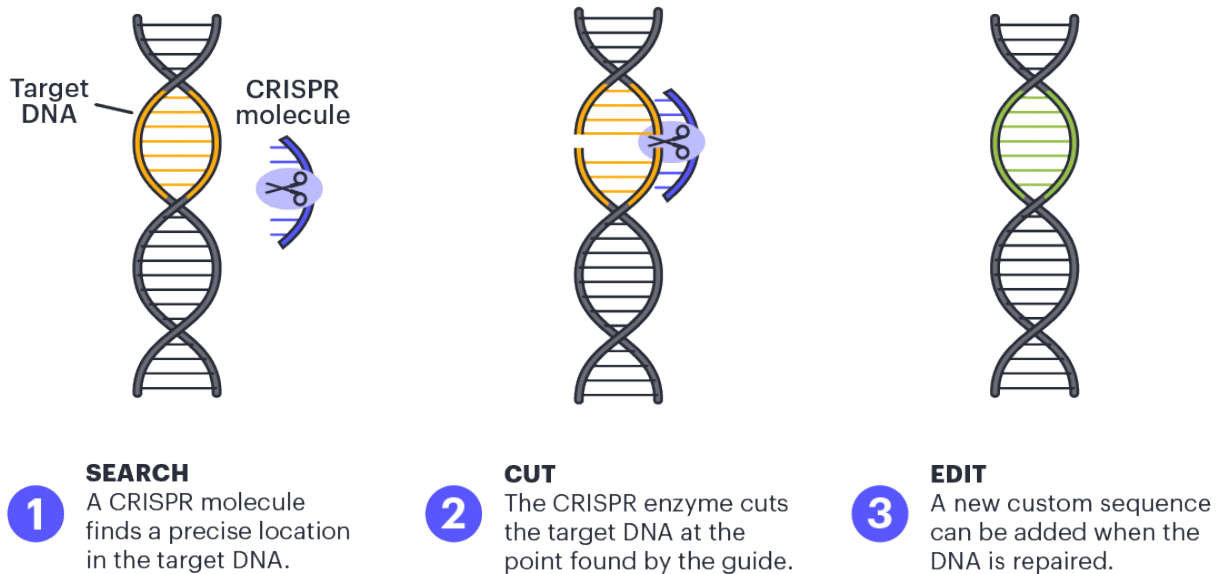**From the IGI's ["What is CRISPR?"](#)**

DNA is the instruction manual for life on Earth. It encodes the fundamental properties of an organism — how it lives, grows, and reproduces. Changing a DNA sequence in a living cell is known as [genome editing](#) or [gene](#) editing. For a long time, this was either impossible or extremely challenging.

The discovery of CRISPR [genome](#) editing has made this process much easier. In 2012, research by IGI founder Jennifer Doudna, Emmanuelle Charpentier, and their teams developed a method of repurposing a [bacterial](#) immune system called CRISPR — an acronym that stands for Clustered Regularly Interspaced Short Palindromic Repeats — to make breaks in DNA at precise locations, using a CRISPR-associated [enzyme](#) (the Cas9 [protein](#)) like molecular scissors to cut DNA.

Scientists can now edit the genome of living organisms by adding new fragments of DNA for the cell to use as

a template when it repairs the break in the DNA. In this way, scientists can replace a disease-causing [mutation] with a healthy sequence or make other modifications to the genome.

Alternatively, scientists can use this method to "knock out" a gene entirely — a technique that is frequently used to study the functions of genes — or to modify portions of the genome that affect how genes are [expressed], known as "[epigenetic] editing." Together, these methods give scientists powerful new tools to treat disease, improve agriculture, and study fundamental questions of biology.

SEARCH
1 A CRISPR molecule finds a precise location in the target DNA.

CUT
2 The CRISPR enzyme cuts the target DNA at the point found by the guide.

EDIT
3 A new custom sequence can be added when the DNA is repaired.

Source: Innovative Genomics Institute

Connecting science and societal benefits
Gene editing is a powerful technology that has the potential to do immense good, but only if implemented safely and in the right contexts. Applying gene editing technologies requires much more than just technological advances – it requires the appropriate sociopolitical landscape, regulatory and safety standards, resources, and public trust. To that end, **societal engagement** around gene editing is critical.

REFERENCES & RESOURCES

Resources on science, innovation and public engagement

Below are a selection of resources and references that users of this toolkit may find useful. In no way do these links constitute the entirety of important and useful scholarship and resources out there, but we hope they give a slice of relevant information.

For recommended general reading on collaborative problem solving and facilitation strategies applicable to a wide variety of science-policy issues, check out the common higher ground resource guide available for free download at Common Higher Ground Workshop - Keystone Policy Center.

PUBLICATIONS AND ARTICLES

Genome-edited crops for improved food security of smallholder farmers (Nature Genetics, 2022)
> *Perspectives on genome-edited crops and their potential benefits to smallholder farmers, as well as possible risks – technical and societal – of edited crops. Includes an assessment of the EU's policy on gene-edited crops.*

Gene editing and agrifood systems (FAO, 2022)
> *Summary of the state-of-the-field of gene-editing in agriculture and food systems by the Food and Agriculture Organization of the United Nations. Outlines several scenarios in which gene-editing could be beneficial for improving food security globally.*

Designing Participatory Technology Assessments: A Reflexive Method for Advancing the Public Role in Science Policy Decision-making (Technological Forecasting and Social Change, 2021)
> *A framework for bringing public participation into science policy decisions, called participatory technology assessment (pTA) developed by the Consortium for Science, Policy & Outcomes.*

Public and Stakeholder Engagement in Developing Human Heritable Genome Editing Policies: What Does it Mean and What Should it Mean? (Frontiers in Political Science, 2021)
> *A deep dive on effective public and stakeholder engagement strategies for crafting effective policy around heritable human gene editing. Authors conduct a critical review of engagement campaigns undertaken by a few agencies and evaluate them based on five ideals: comprehensiveness, transparency, inclusivity, sound methodology, and accountability.*

Responsible governance of gene editing in agriculture and the environment (Nature Biotechnology, 2021)
> *An article that lays out potential governance principles for the responsible and effective use of gene-editing technology in products. Outlines the pitfalls of genetically-modified foods and ways in which they could be avoided in the case of gene-edited foods.*

[Societal Debates About Emerging Genetic Technologies: Toward a Science of Public Engagement](#) (Environmental Communication, 2020)

> *Perspectives on how to best engage with the public on the "wicked problem" of gene-editing, including specific recommendations for bench scientists as well as social scientists. Argues the need for more meaningful and intentional engagement as early as possible.*

[Emerging Technologies for Invasive Insects: The Role of Engagement](#) (Annals of the Entomological Society of America, 2020)

> *A detailed assessment of engagement in the field of invasive insect management. The authors outline best practices for engagement in three main steps: 1) pursue engagement across decision phases and sectors; 2) select context-appropriate participants and methods; and 3) recognize and navigate engagement-related tensions. They use a specific case of an invasive fruit fly as an example of effective ongoing and future engagement.*

[Online Representations of "Genome Editing" Uncover Opportunities for Encouraging Engagement: A Semantic Network Analysis](#) (Science Communication, 2019)

> *A semantic analysis of representations of genome-editing in two online networks, Google and Wikipedia. The findings show that, thus far, most of the information related to the technology focus on technical information rather than social or moral debates.*

[Mice Against Ticks: an experimental community-guided effort to prevent tick-borne disease by altering the shared environment](#) (Philosophical Transactions of the Royal Society B, 2019)

> *An experiment to prevent tick-borne disease transmitted by mice in Nantucket and Martha's Vineyard, two island-based communities in eastern North America. The study aims to release mice engineered to be immune to pathogens that infect ticks on the island, thereby significantly lowering the affected tick population. The study employed community engagement campaigns from the outset to determine the ideal strategy, which is detailed in the paper, and serves as a good example of how community engagement can be incorporated into the research design.*

[Genetic frontiers for conservation: An assessment of synthetic biology and biodiversity conservation: technical assessment](#) (IUCN, 2019)

> *This report is published by the International Union for Conservation of Nature (IUCN) Task Force on Synthetic Biology and Biodiversity Conservation, and offers an extensive and highly detailed analysis of using synthetic biology tools in conservation and genetic diversity. The report is a critical assessment of the range of issues surrounding this approach, including current technologies, risk/benefits, governance, societal impact, and long-term implications. A shorter summary of the report can be found here.*

CRISPR versus GMOs: Public acceptance and valuation (Global Food Security, 2018)
> A study of public acceptance of gene-edited rice vs GMO rice. The study has many interesting findings, such as respondents were more willing to eat CRISPR food over GM food, but without detailed information respondents' valuation of CRISPR and GM food overall was similar. Furthermore, the study assesses how respondents reacted to different labeling policies, pricing, and contexts.

Rethink public engagement for gene editing (Nature, 2018)
> *Offers a new structured approach to gene-editing engagement, namely creating a consortium of interested parties, including scientists, policymakers, activists, private companies, etc. from all perspectives that can address concerns and inform the public.*

A framework for enhancing ethical genomic research with Indigenous communities (Nature Communications, 2018)
> *Details a framework for how to engage with Indigenous communities regarding genomics research, using six principles: (1) understand existing regulations, (2) foster collaboration, (3) build cultural competency, (4) improve transparency, (5) support capacity, and (6) disseminate research findings.*

CRISPR for Crop Improvement: An Update Review (Frontiers in Plant Science, 2018)
> *A very thorough review of CRISPR use-cases in several crop plants, such as rice, wheat, maize, cotton, soybean, tomato, potato, grape, and citrus. Mostly technical breakthroughs and updates.*

Biotechnology, the American Chestnut Tree, and Public Engagement Workshop Report (Genetic Engineering and Society Center, North Carolina State University, 2018)
> *A detailed report of the public engagement workshop for the restoration of the American Chestnut using genetically-engineered varieties. Includes engagement strategies, participant opinions, summary of findings, and recommendations.*

Communicating through vulnerability: knowledge politics, inclusion and responsiveness in responsible research and innovation (Journal of Responsible Innovation, 2016)
> *An article that uses three case studies to argue that idealized rational decision-making is not sufficient for responsible innovation, but rather needs, vulnerabilities, identity, and agency are entangled within society and must be factored into scientific innovation.*

Responsible innovation and the reshaping of existing technological trajectories: the hard case of genetically modified crops (Journal of Responsible Innovation, 2016)
> *An article that argues the need to move away from a "risk assessment" discussion of genetically-modified crops and into one that encompasses historical, cultural, societal perspectives. Also refutes the information deficit model of public acceptance of GM crops as being far too simplistic, despite being prevalent.*

Rewriting the Code of Life (New Yorker, 2016)
> *A long-form essay that features a gene-drive scientist, Dr Kevin Esvelt, as a vehicle to discuss bioethics, the academic community, and public engagement.*

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[Developing a framework for responsible innovation](#) (Research Policy, 2013)

> *This article describes the original framework of responsible research and innovation. The authors synthesize previous findings and perspectives on public governance of research into four main pillars: anticipation, reflexivity, inclusion, and responsiveness. This framework is the basis for a lot of thinking for best practices in linking engagement with innovation, and continues to be relevant.*

[Public Engagement with Biotechnologies Offers Lessons for the Governance of Geoengineering Research and Beyond](#) (PLOS Biology, 2013)

> *A case study that employs the framework described in the paper above, involving a geoengineering experiment to manipulate the level of sunlight received in an area. Describes the engagement process in detail.*

ORGANIZATIONS AND TOOLKITS

[Association for Responsible Research and Innovation in Genome Editing](#)

> *ARRIGE is an international organization based in France that seeks to bring together all stakeholders to promote a global governance strategy for genome-editing, and its responsible and ethical use. They have published statements on [regulation of gene-edited crops, gene drive technology, and edited human embryos.](#)*

[Boston Museum of Science Public Engagement with Science Guide](#)

> *The Boston Museum of Science has compiled a guide for public engagement with science after many years of work in this field. As described on the website, "This guide is designed to help staff at informal science education organizations and others who are interested to develop, implement, and evaluate activities and events that incorporate the multi- directional dialogue and mutual learning at the heart of public engagement with science."*

[Consortium for Science, Policy & Outcomes](#)

> *The Consortium for Science, Policy & Outcomes (CSPO) is an organization that develops projects, practices, and knowledge bases to enable the scientific enterprise to interact more effectively with the public and society. CSPO has several active projects on their website, including [public engagement on human genome editing and carbon dioxide removal technologies](#). They have also developed a framework for bringing public participation into science policy decisions, called [participatory technology assessment (pTA).](#)*

[Global Citizens' Assembly on Genome Editing](#)

> *The Global Citizens' Assembly is an international project to bring together representative stakeholders from multiple countries to inform, deliberate, and recommend governing principles for gene-editing. The product of the deliberations will be presented to the UN, WHO, FAO, and national leaders, and will also be featured in a [documentary film](#) recording the process.*

Genetic Engineering and Society Center

The GES is a center based at North Carolina State University dedicated to interdisciplinary research in genetic engineering and its societal impact. Part of the core mission is to engage with the public, identify problem areas, perform risk-assessment for research, and facilitate dialogue between scientists and stakeholders. Some of their projects include collecting an oral history of agricultural genetic engineering practices, assessing the institutional and regulatory frameworks surrounding CRISPR gene editing in Latin America and the Caribbean, and a workshop on gene drives in agriculture exploring the risks and benefits.

Keystone Policy Center

Keystone Policy Center is a non-profit, non-advocacy organization with a mission to inspire leaders to rise above entrenched positions to reach common higher ground. Keystone is recognized by public, private, and civic-sector leaders for independent, collaborative problem-solving approaches on a variety of science-policy issues in agriculture, natural resources, health, Tribal and Indigenous engagement, and education. Keystone offers capacity building, engagement and collaboration training and also leads work in incorporating diverse societal perspectives into responsible governance approaches for emerging genomic technologies and their applications in food, agriculture, the environment, public health and personal medicine.

International Association for Public Participation, USA

IAP2 is an organization that advocates for public participation in decision making. They provide tools for practitioners (researchers, policymakers, community leaders) to effectively include, collaborate with, and empower stakeholders. IAP2 has developed three Public Participation Pillars that outline a plan for social engagement.

Involve UK

Involve UK is a UK-based organization founded to facilitate public engagement in policy decision-making. They have an extensive catalog of projects and resources available on their website, including a descriptive list of various methods of public engagement at different levels.

Responsible Research and Innovation

RRI is a set of guiding principles that are meant to be employed "upstream" of any research enterprise, to incorporate societal values and impacts into the design, in order to align research goals with the goals of society at large. The RRI website has an extensive database of resources, including trainings, examples, and community forums to integrate RRI into any research environment or plan.