

Concept Clearance

Branch: Population Health Branch

Council Period: 202301

Concept Title: Reporting Back Environmental Health and non-Genomic Research Results

Introduction

Reporting back environmental health research results, including non-genomic information, to study participants has been an evolving discussion with different perspectives for nearly 20 years. Recent national conversations have taken place and informed general recommendations on next steps for ensuring ethical, timely, and appropriate report-back. The Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) commissioned the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a study and generate a report, from a consensus body of experts representing diverse perspectives, that reviews and evaluates the ethical, societal, regulatory, and operational issues related to report-back of individual-specific research results generated from research on human biospecimens. The 2018 NASEM report, [“Returning Individual Research Results to Participants,”](#) outlined many recommendations including that reporting-back of findings to communities and individuals should be routinely and appropriately considered as a matter of reciprocity, respect, transparency, and trust. At the same time, the National Institute of Environmental Health Sciences’ (NIEHS) Partnerships for Environmental Public Health (PEPH) network hosted a meeting, [“Reporting Back Research Results,”](#) where participants highlighted the importance of training and guidelines to ensure proper report-back of results. In January 2022, NIEHS and the National Human Genome Research Institute (NHGRI) co-hosted a meeting [“Ethical, Legal, and Social Implications of Gene-Environment Interaction Research,”](#) to explore ELSI in research endeavors related to gene-environment interaction (GxE) and genetic susceptibility to environmental exposures. Meeting participants emphasized how community concerns should inform and guide report-back of results and that there is a need for community engagement, guidelines, and further educational resources for effective communication of research results. Additionally, the NIEHS dedicated time at its National Advisory Environmental Health Sciences Council (NAEHSC) meetings in February and June 2022 to discuss opportunities to advance work in this area. The Council agreed with three identified opportunities for action: training, guidelines, and resources.

The research enterprise is increasingly moving towards greater return of individual-specific research results to increase the value for participants and improve scientific rigor and reproducibility. While commonly discussed in relation to return of genomic research results, there has been a growing movement toward greater report back of environmental and non-genomic research results. There are recognized challenges in returning research results. As such, there is a need for research to inform community engagement, guidelines, and additional educational resources for effective communication of research results to individual participants and, as appropriate, aggregate results to other key partners, such as Community-Based Organizations, Tribal Nations, Public Health Departments, schools, faith-based organizations, community workers, health care providers, policy makers, and Institutional Review Boards.

Research Goals and Scope

Key objectives of the proposed concept are to:

- Advance the science of report-back of environmental health research and other non-genomic research results to establish best practices/guidelines through research and evaluation.
- Identify preferences, perceived risks and benefits, barriers and facilitators related to reporting back research results. Use these new insights to inform the evolving practice of RBRR.
- Recognize the role of RBRR in reducing health disparities and advancing health equity.

Informed by the outcomes of the above-mentioned meetings, the proposed concept intends to focus on the following three cross-cutting research areas: Health Equity, Communication Approaches, and Use of Data Reported Back. We would expect proposals to address two of these three areas.

In addition, proposals would need to clearly articulate and address a bioethical issue related to RBRR, such as, but not limited to: data sharing, participant privacy, potential stigma and/or discrimination associated with identification of subpopulations at risk due to environmental exposures or genetic susceptibility to environmental exposures.

Outcomes/Scientific knowledge to be gained

We envision that this new concept, if approved, would help to advance the science of reporting back environmental research and non-genomic research results. It would provide us with better understanding of different perspectives of RBRR and how environmental health and non-genomic data can be returned to participants and communities effectively. In addition, the program would help to nurture new tools and approaches to RBRR or testing of existing approaches in different settings. The proposed concept is positioned to highlight the necessary supports, training, and guidance to ensure feasible, appropriate, and quality RBRR. Finally, it is hoped that the program would enable consistency of RBRR across institutions and provide IRBs with necessary information to help with their decision making.

Mechanism and Justification

We are proposing the use of the R01 grant mechanism to enable appropriate multi-disciplinary research and testing of different tools and approaches. We would expect to see proposals that combine qualitative and quantitative research to address the topics and issues outlined. Community-engaged approaches would be encouraged, and if proposed, would need to demonstrate the authenticity of the partnership.

Anticipated number of awards: 4-5

We are proposing a NIEHS program budget of up to \$1.5M annually for 4 years. We are partnering with the NIH Office of Science Policy, and they propose a program budget of up to \$800K annually for 4 years. We have reached out to other partners who have expressed an interest in this concept.

Timeline

We are proposing the following timeline:

February2023	Concept Clearance to Council
April 2023	Publish Funding Opportunity Announcement
Summer 2023	Application Receipt Date
Fall 2023	Review Applications
February 2024	Program Plan to Council
Spring 2024	Award grants