

Concept Clearance

Branch: Population Health Branch

Council Period: 201905

Concept Title: Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21)

Introduction

Every community is vulnerable to natural and man-made disasters and other emerging environmental or public health threats. Disasters such as Superstorm Sandy, the Deepwater Horizon oil spill, and the Flint, Michigan water crisis highlight the need for rapid data collection on exposures or stressors to better assess their impacts on human health. To address this need, NIEHS created the Time-Sensitive Research Grants Program, with the intent to support research to understand the human health effects of these events through rapid collection of environmental and human biological samples as well as human health data. Overall, these data are expected to provide critical information to understand exposure-health outcome relationships, facilitate timely action to protect human health, and better understand the short- and long-term health consequences following disasters.

Beginning in 2010, NIEHS issued Program Announcements for the time-sensitive program. During this time NIEHS received 84 applications and funded 13. Some of the funded topics include the Assessment of a clean heat policy in NYC; Perception of exposure risk of Navajo communities to the Gold King Mine spill; Health and air pollution near urban oil drilling sites; Health effects of the Gulf oil spill; and the Effects of hurricane Sandy on respiratory and mental health of World Trade Center responders. In 2016 the time-sensitive program was issued through a Request for Applications (R21), with monthly receipt dates. Changes over time to the way the program has been implemented have reduced the average time of receipt to award from six months to 90-120 days. For very large events such as the recent hurricanes, we have issued a guide notice to remind investigators of the availability of the program to support research on that event but within a limited period of time.

Research Goals and Scope

The Time-Sensitive research program is intended to support environmental health research in which an unpredictable event provides a limited window of opportunity to collect human biological samples or environmental exposure data. The primary motivation of the FOA is to understand the consequences of natural and man-made disasters or emerging environmental public health threats in the U.S. and abroad. A distinguishing feature of an appropriate study is the need for rapid review and funding (substantially shorter than the typical NIH grant review/award cycle) for the research question to be addressed and swiftly implemented.

The proposed research project may be in any area of science considered to fall within the NIEHS mission and meets the requirements of the FOA. Leveraging existing cohorts or community partnerships is encouraged.

Examples of research that could consider submission to this program include natural disasters, industrial accidents, terrorist attacks, and major policy changes affecting air or water quality.

Mechanism and Justification

The traditional application process requires 8-12 months from application submission to award. However, there are instances where a research opportunity would be lost if the project were delayed that long.

The primary purpose of this program is to support the collection of human samples or exposure data within a short period of time following a qualifying event. It was not intended to be a full-fledged research project. With the time-constraints on submitting applications to maintain time-sensitivity, the R01 has not been considered an appropriate mechanism. Therefore, the mechanism selected was the R21 which supports exploratory and developmental research projects, providing a total of \$275,000 direct costs over a two-year period with no more than \$200,000 in one year. The use of this mechanism enables investigators to reach study areas to do the data/sample collection and analysis that can be used to support the assessment and human health impact of the event and provide the preliminary data that could be used to support longer term studies if appropriate.

The mechanism options have been revisited prior to each re-issuance of the program. However, as applications submitted to this FOA are expected to conduct innovative research, within a limited time frame, that will lay the foundation for improved population studies concerning the effect of environmental agents on health, the R21 continues to be the most appropriate mechanism.

Program Management

The program has a standing committee that is comprised of a program coordinator, a program officer from each program branch, the deputy division director, and a program branch chief. To help reduce the time from receipt to award, the FOA requests a letter of intent (LOI) from the investigator, which provides the scientific review officer (SRO) information on the number of applications expected to be submitted. The SRO sends the LOI to the program coordinator. If the LOI lacks sufficient information to determine responsiveness, additional information is requested from the investigator which is then reviewed by the time-sensitive committee. Applications received from investigators whose LOIs were considered responsive, are reviewed by a special emphasis panel convened by an NIEHS SRO generally within six weeks of the receipt date.

Applications that are received without an LOI also undergo an administrative review for responsiveness. Applications deemed non-responsive are withdrawn without review after informing the investigator of the decision.

Post review, applications that fall above the pay line but within the zone of consideration are offered the opportunity to provide a response to the summary statement, which can be used by the program officer to raise the application for special consideration for funding. Following Council, funding decisions are made by the division director in conjunction with the coordinator and program officers.