Time-Sensitive Opportunities for Health Research

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Overview of concept

- **Concept Clearance Title:** Time-Sensitive Opportunities for Health Research
- **Objective/Purpose:** To establish an expedited funding opportunity to support rigorous and novel “time-sensitive” research to understand behavioral and health outcomes related to unexpected events.
  - “Event” refers to federal, state or local policies; natural events/disasters; or infrastructure changes/changes to the built environment.
- **Project Mechanism:** PAR for R61/R33 phased award (clinical trial not allowed)
- **Award Project Period:** Maximum of 5 years
  - ≤ 2 years (R61); ≤ 3 years (R33)

Background

- Past NIH time-sensitive mechanisms have supported projects related to obesity policy and program evaluation, drug and alcohol abuse research, and natural event or environmental disasters.

- OBSSR-led workgroup identified interest in, and need for, a broad, cross-cutting funding opportunity to support “time-sensitive research” at multiple ICs.
  - Working group represents 12 ICOs and includes Program Officers and SROs who played key roles for review and administration of past time-sensitive grants.

- Potential ICO partners

NCI	NIAMS	NIEHS
NIA	NICHD	NINR
NIAAA	NIDA	ODP
NIAID	NIDDK	

“Time-sensitive” criteria

- Time-sensitive event: Change in program, policy, or infrastructure that unexpectedly arises in a particular community/population.
- Defining features of “time-sensitive research” include:
  - Unpredictable and unanticipated nature of the data collection opportunity,
  - Clear scientific value and feasibility of proposed study,
  - Limited time to collect key data (a potential missed opportunity), answer key research questions, or begin to prospectively evaluate a new policy/program that impacts health-related outcomes in a given population.
- Time-sensitive research necessitates a shorter-than-typical review and award process (4-5 months versus 9-10 months), and is unlikely to occur without expedited review and funding.

Examples of Funded Projects from Active Grants

- **PAR-18-854:** Time-Sensitive **Obesity** Policy and Program Evaluation (R01 Clinical Trial Not Allowed)
  - The Impact of Salad Bars on Dietary Consumption Patterns in Elementary School Students
  - Evaluating A Healthy Restaurant Kids Meals Policy
- **PAR-19-064:** Mechanism for Time-Sensitive **Drug Abuse** Research (R21 Clinical Trial Optional)
  - Measuring the Public Health Impact of State-Level Flavored Tobacco Bans on Youth and Adult Tobacco Use
  - Impact of SB 273 on West Virginia Patients, Providers, and Overall Prescription Rates of Opiate Medications
- **RFA-ES-19-011:** Mechanism for Time-Sensitive Research Opportunities in **Environmental Health** Sciences (R21 Clinical Trial Not Allowed)
  - Impacts of Hurricane Dorian on coastal seafood resources and safety
  - Evaluation of California's 2020 chlorpyrifos cancellation on health and exposure in agricultural communities

COVID-related examples from active grants

- COVID-19 Policies: Impact Over Time on Child Health, Obesity, and Disparities
- The Impact of COVID-19 Related School Closures on Children's Weight Status
- Identifying and Testing Post-Overdose Outreach Adaptations to Enhance Survivor Engagement During the COVID-19 Pandemic
- The External Exposome and COVID-19 Severity
- Investigating linkages between arsenic exposure, diabetes, and COVID-19 infections and risks on the Navajo Nation
- Per- and Polyfluoroalkyl substances (PFAS) Exposures and COVID-19 in Firefighters

Example: Time-Sensitive Obesity Policy and Program Evaluation (R01)

- **Project Title:** Impacts of Later High School Start Times on Adolescent Weight and Weight-Related Behavior (5R01HD088176-04)
- **Purpose:** To evaluate the impacts of policy changes in two MN school districts (shifting high school start times) on obesity-related behaviors and outcomes in adolescents.
- **Benefit of time-sensitive grant:** Researchers were able to launch baseline data collection (pre-policy) via their "START" survey before the end of the school year.
- **Impact:** 7 publications
  - Widome R, et. al. Association of Delaying School Start Time With Sleep Duration, Timing, and Quality Among Adolescents. *JAMA Pediatrics* 2020;174(7): 697-704.
  - Berger AT, et. al. Relationships between sleep duration and adolescent depression: a conceptual replication. *Sleep Health* 2019;5(2): 175-9.

Example: Mechanism for Time-Sensitive Drug Abuse Research (R21)

- **Project Title:** Impact of SB 273 on West Virginia Patients, Providers, and Overall Prescription Rates of Opiate Medications (1R21DA049861-01)
- **Purpose:** The purpose of this study is to utilize quantitative and qualitative measures to determine the effect of the recent opiate prescription laws in West Virginia. The goal is to discern the effect of changes in state opiate prescribing policy on prescribing practices.
- **Benefit of time-sensitive grant:** The time-sensitive mechanism allowed for expedited funding to support baseline data collection of opiate prescribing habits before the law on prescribing limits was fully enacted.
- **Impact:** 1 publication
  - Sedney CL, et.al. Assessing the impact of a restriction opioid prescribing law in West Virginia. *Substance abuse treatment, prevention, and policy 2021;16(1):14.*

Example: Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

- **Project Title:** Per- and Polyfluoroalkyl Substances (PFAS) in Marine Fish and Shellfish: A biomonitoring tool for PFAS remediation and a metric for potential human exposure through seafood consumption (1R21ES032187-01)
- **Purpose:** To investigate the relationship between PFAs exposure and human health outcomes through measurement of regionally-sourced seafood species and local seafood consumption habits.
- **Benefit of time-sensitive grant:** Grant funding enabled immediate data collection in response to rapidly evolving regulations on PFAs use, surface water standards, and remediation efforts at contaminated sites in New England. Researchers demonstrated an urgent need to collect baseline data in order to properly evaluate the effectiveness of these exposure reduction policies.
- **Impact:** 1 publication
  - Cleary BM. et. a.l. Comparison of Recreational Fish Consumption Advisories Across the USA. *Current Environmental Health Reports* 2021;8(2): 71-88.

Key Considerations in FOA Development

- Focus on methodological rigor within the context of natural experiments
  - Primary data collection for baseline/pre-implementation data
  - Quasi-experimental, quantitative or mixed-methods study designs
  - Examples include: Difference-in-difference (DID) designs, interrupted time-series (ITS), group panel data designs, regression discontinuity
  - Inclusion of comparison group strongly encouraged, when feasible
- Strict responsiveness criteria
  - Clear timeline with expected research milestones and feasibility plan
  - Justification for time-sensitivity of proposed research
- Establishment of relevance and generalizability of study findings for U.S. populations

- **Potential Impact**
  - Research is expected to have generalizability at the state or national level, and to inform our understanding of the impact of program/policy changes in the near-term.
  - Projects supported by this mechanism will inform healthcare, public health efforts, and policy-related decisionmakers about the population effects of policy and program variations/implementation in a timely and far-reaching way.

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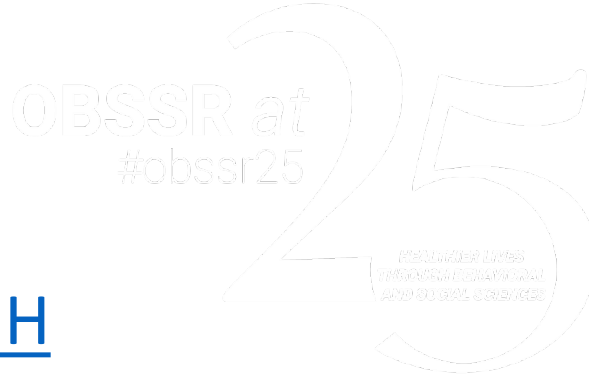

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