

Pre-Application Webinar: PAR 22-115 and PAR 22-120:

Research on Community Level Interventions for Firearm and Related Violence Injury and Mortality Prevention (CLIF-VP)

Dara Blachman-Demner, PhD (OBSSR)

Jessica Bellinger, PhD (Center for Scientific Review)

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<p>Bob Freeman, PhD National Institute on Alcohol Abuse and Alcoholism (NIAAA)</p>	<p>Barbara Oudekerk, PhD National Institute on Drug Abuse (NIDA)</p>
<p>Christine Ulbricht, PHD, MPH National Institute of Mental Health (NIMH)</p>	<p>Jennifer Alvidrez, PhD Office of Disease Prevention (ODP)</p>
<p>Elizabeth Barr, PhD Office of Research on Women's Health (ORWH)</p>	<p>Christopher Barnhart, PhD Sexual and Gender Minority Research Office (SGMRO)</p>



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Webinar Tips

Participants will be in Listening Mode and will not be able to ask questions verbally or use the "Chat" function.

Participants must ask questions using the "Q and A" feature. Questions will be answered during the Q&A session at the end of the webinar as time permits.

These slides and a recording of today's webinar will be available on the OBSSR website:

<https://obssr.od.nih.gov/about/violence-research-initiatives>



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Agenda

- I. PAR Background, Objectives, and Expectations
- II. Peer Review Process
- III. Timeline for Submission, Review, and Selection of Applications
- IV. Participant Questions



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Part I:

PAR Background, Objectives, and Expectations

Dara Blachman-Demner, Ph.D.
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Objective and Network Structure

- Objective: to support a network of research projects to develop and test prospective interventions at the community/community organization level that aim to prevent firearm and related violence, injury and mortality.
- Expected to include up to 10 cooperative agreement (UG3/UH3) research projects (PAR-22-115) and a U24 Coordinating Center (PAR-22-120)
- U24 Coordinating Center (CC) to support
 - Administration, coordination, and communication
 - Data, measurement, and analytics support and consultation
 - Public/stakeholder engagement and dissemination support



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Network Structure (cont.)

- Steering Committee (SC) to provide overall governance and guide cross-project activities
 - At least two representatives from each Research Project (academic PI and community PI/key personnel) and the CC and NIH science officers
 - Meet at least once a month with workgroups as needed
 - Joint activities may include: coordination of research protocols, human subjects/regulatory protocols, data harmonization and archiving, manuscript/information dissemination planning (including initial clearance of collaborative network projects).



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Key Definitions

- ***Community***: A specific group of people, often living in a defined geographic area, who share a common culture, values, and norms and who are arranged in a social structure according to relationships the community has developed over a period of time.
 - May be self-defined or defined by the catchment area of local government or service providers
 - Virtual or other communities that do not reside in the same geographic location are not included.
- ***Community organization***: A non-Federal, non-academic organization that provides goods, services, support, resources, or advocacy to members of a defined community



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Background

- Violence is a public health condition linked to social determinants of health over the lifespan
 - Firearm homicide is the 3rd leading cause of death among persons aged 10 to 24 years, the leading cause of death among young Black men and the 2nd leading cause of death for Hispanic youth.
 - Pregnant women in the United States died by homicide (most often from partners) more often than they died of pregnancy-related causes.
 - Most preventive interventions remain focused on “high-risk” individuals and/or are delivered in group settings
- There is a critical need for community/community organization level preventive interventions that engage partners in meaningful ways



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Potential Research Questions

- What **new and innovative violence intervention practices** can be developed from existing theory and/or **basic social and behavioral research** that would provide additive or complementary effectiveness to existing programs and practices?
- How can the type and dose of various intervention components be **combined and/or sequenced** to optimize effectiveness and/or adoption potential in a broad range of communities to reduce violence, especially firearm violence?
- What role do the **unique contextual factors** of communities play in enhancing or inhibiting the potential effects of intervention programs?
- How do various sources of **adaptation** within a range of community contexts impact the effectiveness of the intervention on both (firearm) violence prevention and implementation outcomes?
- What are the community, organizational and **contextual level barriers and facilitators to adoption**, scale up, and sustainability of programs and practices and what are the best implementation strategies to address those barriers?



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Community/Community Organization (CO)-Level Interventions

- An intervention that modifies community-level or community organization/institution characteristics.
- This could include, but is not limited to:
 - The physical/built environment (e.g., vacant lot/abandoned building restoration)
 - The social environment (e.g., community investment in private/public spaces)
 - Policies/practices of organizations, institutions or governmental agencies that have community-level health impacts (e.g., policies to reduce the density of alcohol outlets; alternatives to incarceration)
 - Norms or collective behaviors of community residents (e.g., community surveillance efforts, bystander de-escalation strategies) or individuals within community organizations.



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Community/CO-Level Interventions

- **What does NOT constitute a community/CO-level intervention?**
- Interventions that are delivered in community settings and/or use community-based outreach/enrollment but intervene at the individual level and do not target community/CO-level determinants of health
- An intervention that focuses exclusively on helping individuals or populations cope with the impacts of violence and do not directly address community- or organizational-level root causes of the violence
- An intervention that includes community/community organization-wide elements, but intervention effects are tested only at the individual, peer, or family level



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Research Expectations: Required

- Led by or conducted in collaboration with appropriate community organizations.
 - Key personnel/budget/joint development of the research and intervention plan.
- Prospectively test the impact of the intervention on firearm and related violence and victimization outcomes.
- Collect data beyond individual self-report to determine how the intervention is impacting community- or organizational-level determinants.

Note: For NIMH, applications must be consistent with NIMH priorities for research on violence and aggression towards others as described in [NOT-MH-22-095](#).



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Research Expectations: Encouraged

- Multi-sectoral (e.g., education, health, criminal legal, social services) collaborations with public and private stakeholder organizations
 - Interventions focused solely on the health care setting are not a priority
- Guided by conceptual model identifying hypothesized pathways between the community/community organization level intervention, determinants, and violence related injury or mortality.
 - Appropriate measures and analytic methods to examine community- and organizational-level mechanisms of action and violence related outcomes.
 - Be supported by relevant preliminary data from at least one setting
 - Include assessment of relevant and intersecting social determinants of health



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Non-Responsive Criteria (PAR 22-115)

- Projects that do not include specific aims for both a UG3 and a UH3 phase and a well-defined set of milestones for each phase
- Projects that focus exclusively on virtual or other communities that do not reside in the same geographic location.
- Projects that do not prospectively test a community level intervention.
- Projects that do not include baseline data (i.e., prior to the implementation of the intervention) on the outcomes of interest in the populations receiving the intervention.
- Projects that use only individual-level data or are exclusively qualitative.
- Projects that do not involve one or more community partners as key personnel and/or proposed subcontracts to collaborating institutions.
- Projects that propose data collection or testing of interventions outside of the U.S.
- Projects that include prohibited policy lobbying or advocacy activities (see https://grants.nih.gov/grants/lobbying_guidance.htm for more information).



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***It is strongly recommended that you reach out to the relevant PO prior to submission.
Non-responsive applications will not be reviewed.***

UG3/UH3 Phased Innovation Awards

- Bi-phasic projects for up to five years:
 - UG3 (Phase 1):
 - One to two year award
 - Milestone-driven exploratory study to demonstrate sufficient preparation, feasibility, capacity and leveraging of foundational activities needed for the implementation studies planned in Phase 2 (UH3)
 - Includes scientific, operational and collaborative planning activities as well as tangible deliverables/preliminary findings
 - UH3 (Phase 2):
 - Three to four years of support for the implementation and evaluation of the interventions or strategies planned/developed in the UG3 phase



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UG3/UH3 Phased Innovation Awards (cont.)

- Projects that have met the milestones for the UG3 phase will be considered and prioritized for transition to the UH3 phase
 - Funding of the UG3 does not guarantee support of the UH3 award
 - All funded UG3 projects may not transition to the UH3 phase
 - Transition will be determined by the availability of funds and the outcome of a programmatic evaluation at NIH
 - Appeals of the transition decision will not be accepted



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U24 Coordinating Center Award

Three categories of activities:

- 1) Administration, coordination, and communication:
 - Logistics and management support, organizing meetings, maintaining documentation of network activities
 - Establishment of CLIF-VP Research Network Steering Committee to develop policies governing authorship, communications, data sharing, etc.
 - Support communication among the CLIF-VP PIs, NIH staff, Steering Committee, Stakeholder Board, and others
 - Develop and facilitate working groups on network topics of interest
 - Develop an organizational structure to promote collaboration, provide technical assistance, and facilitate interaction across the consortium



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U24 Coordinating Center Award (cont.)

2) Data, measurement, and analytics support and consultation:

- Support data harmonization, sharing and preparing data for archiving
- Provide consultation on harmonizing social determinants of health measures
- Identify, facilitate access to, compile databases (e.g., risk factor, criminal justice, education data) and provide linkages to outcomes to enable CLIF-VP network sites and other researchers to access
- Collate administrative, geo-coded and/or other community level data from projects to facilitate and/or conduct cross-site analyses
 - Integrate different streams of data and develop agreements about the structure of content used across projects
- Provide methodological and statistical consultation on cross consortium and/or individual research project design and analytics as needed.
- Communicate and provide technical assistance, as needed on data sharing, IRB/human subject issues and relevant federal data standards



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U24 Coordinating Center Award (cont.)

3) Public/stakeholder engagement and dissemination support:

- Create and support a Stakeholder Board representing appropriate members of the public, government agencies, relevant communities, systems and settings
- Provide support in exchanging best practices for engagement across communities on recruitment, communications, retention, etc.
 - Identify and address barriers to implementation to facilitate community impact
- Create public facing communications materials (including social media, webpage) designed for study partners to promote the CLIF-VP network
 - Coordinate with other [NIH funded firearms mortality prevention awards](#) and other Federally funded firearms violence prevention programs as appropriate
- Provide support for dissemination activities initiated by the Steering Committee or other network partners
- Lead a multi-modal, theoretically driven effort to rapidly disseminate information generated by the CLIF-VP Research Network, including project updates, lessons learned, and research findings to broad audiences



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Part II:

Peer Review Process

Jessica Bellinger, PhD
Center for Scientific Review, NIH



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Purpose of Peer Review

- To see that grant applications submitted to the NIH are evaluated in a manner that is fair, independent, expert, and timely—free from inappropriate influence—so that the most promising research is funded.
- NIH uses two levels of review as mandated by statute in accordance with section 492 of the Public Health Service Act and relevant federal regulations.
 - First level is by experienced scientists/clinicians with expertise in the relevant disciplines, methodologies, and/or populations for the proposed research areas.
 - Second level is by the IC's Advisory Council, which is composed of both scientific and public representatives chosen for their expertise, interest, or activity in matters related to health and disease.
- Final funding decisions are made by IC Directors in consultation with Program Officials.

Review Process

- NIH's Center for Scientific Review (CSR) will convene a Special Emphasis Panel to review applications in response to [PAR-22-120](#) and [PAR-22-115](#). Applicants do not need to provide a recommended study section assignment.
- Reviews will take place in July.
- All applications will receive a written critique. Only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score.
- Summary statements will be provided 30 days after the meeting completion. The Summary Statement is the official record of the review process and results. It provides a summary of key discussion points that resulted in the Final Composite Score as well as the comments and scores of assigned reviewers

After Application Submission

- **APPLICANT:** Submit before the deadline. Once you have submitted, ensure there are no errors that can still be corrected.
- **RECEIPT BY NIH:** All applications are received and processed by the **Division of Receipt and Referral** at the Center for Scientific Review (CSR). Each application is assessed for completeness and assigned for review, in this case to a Special Emphasis Panel run by CSR.
- **PROGRAM OFFICERS:** Program staff from participating ICs assess the **responsiveness of applications**. Non-responsive applications are withdrawn from review consideration.
- **REVIEW PROCESS:** The **Scientific Review Officer (SRO)** assembles a panel of expert reviewers to conduct the review of technical and scientific merit for the applications.

Confidentiality

- Review materials and proceedings of review meetings represent confidential information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.
- Statute of confidentiality is life long.

Reviewer Conflicts of Interest (COI)

What Constitutes a Reviewer COI?

- Institutional
- Family member/close friend
- Collaborator/Key Personnel
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

http://grants.nih.gov/grants/peer/peer_coi.htm

Review Criteria

5 Scored Review Criteria

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Each scored from 1-9



Overall Impact

Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

Scored from 1-9

Reviewers will evaluate five scored review criteria (Significance, Investigators, Innovation, Approach, and Environment) in the determination of scientific merit and give an Overall Impact score on a scale of 1-9.

Review Criteria

Significance: Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigators: Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

PAR-22-120 Specific Review Criteria

These PARs include unique review criteria. Please read *Section V. Application Review Information* carefully.

Significance: Does the proposed Coordinating Center address the needs of the network that it will coordinate? If fully successful, will completion of the CC's aims improve the engagement of multiple stakeholders (e.g., researchers, communities, systems) in the development, evaluation, adoption, implementation and sustainability of interventions and strategies that are found to be successful in preventing firearm and related violence, injury and mortality?

Investigators: How adequate is the demonstrated capacity, expertise, and productivity within the Coordinating Center?

Innovation: Does the application indicate creativity and flexibility to innovate on an ongoing basis?

Approach: Is the management plan well-described and commensurate with the level of complexity required for the CC? Are the leadership and governance approach, plans for conflict resolution and organizational structure appropriate for the CC? Does the application include an adequate plan for convening the appropriate committees and boards in the CLIF-VP Research Network? Does the CC provide adequate processes for coordinating with NIH and other Federally funded firearms prevention studies as needed? How well does the application demonstrate an understanding of the types of available data related to firearm violence and the challenges underlying the integration of large and complex data sets? How well does the application demonstrate an understanding of and capacity for the statistical techniques necessary to conduct cross-site analyses for a range of data types including: multi-level, administrative, qualitative and quantitative?

Environment: Does the proposed approach account for dynamic change in work environment and how CC will coordinate meetings when in-person meetings may not be viable?

PAR-22-115 Specific Review Criteria

These PARs include unique review criteria. Please read *Section V. Application Review Information* carefully.

Significance: Is a clear and appropriate theoretical basis provided for both the proposed intervention, (including the level(s) of influence addressed), as well as for the process for developing, adapting, and tailoring the intervention to the community proposed? Does the intervention have potential to be sustained after the project is over and/or scalable to other settings?

Investigators: Do the investigators have relevant experience developing/testing/implementing community interventions and working with the community in which the research will be conducted? Do the investigators have relevant experience with conducting multi-site or multi-project studies that require collaboration among project sites such as common protocols and data harmonization? Are the roles and responsibilities of collaborators clearly defined and appropriate? Are appropriate stakeholders, relevant to the population to be included in the research and the system/setting proposed for the project, included on the research team or on the project?

Approach: How well does the research project clearly identify a scientifically justifiable strategy for the UG3 phase of the project? How well does the project's conceptual framework clearly inform the analysis of data and potential pathways for the UH3 phase? How successful is the UH3 phase in proposing strategies and approaches that have a clear pathway from the UG3 data? Are the proposed Timelines and the Transition Milestone well-defined, feasible, quantifiable, and appropriate? Does the application include an adequate plan for participating in the CLIF-VP Research Network Coordinating Center, considering the CC's role to provide administrative coordination, data, measurement, and analytics support and consultation, and public/stakeholder engagement and dissemination support?

Additional Scorable Review Criteria in Assessing Overall Impact

These are not given individual scores but will be considered as a part of the overall impact score.

- Protections of human subjects
- Inclusion plans for sex/gender, race/ethnicity, and age of human subjects across the lifespan
- Appropriate use of vertebrate animals
- Management of biohazards

Review Contact

- If you have additional questions specifically about the review process for these applications, please contact:

Jacinta Bronte-Tinkew, PhD

Jacinta.bronte-tinkew@nih.gov

301-806-0009

Resources for Grant Submission or Peer Review

- Resources for using eRA Commons
 - <https://era.nih.gov/sites/default/files/eRA-Commons-Resources.pdf>
- Problems with Submission Processing
 - Always contact eRA Service Desk at <http://grants.nih.gov/support/>
- Peer Review
 - The Center for Scientific Review (CSR) has produced several videos that provide an inside look at peer review process, on evaluating applications for scientific and technical merit and with tips for preparing applications.
 - https://era.nih.gov/era_training/era_videos.cfm

Part III:

Timeline for Submission, Review, and Selection of Applications

Dara Blachman-Demner, PhD
Office of Behavioral and Social Sciences Research (OBSSR)



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Timeline

- Letter of Intent Due Date: March 22, 2022
- Application Due Date: April 22, 2022
- Peer Review Meeting: July 2022
- Council Review: August 2022
- Start Date: September 2022



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Contacts

- **General/Triage:** Dara Blachman-Demner, OBSSR
- **NICHD:** Valerie Maholmes
- **NIA:** Melissa Gerald
- **NIMHD:** Crystal Barksdale
- **NINR:** Shalanda Bynum
- **NCCIH:** Lanay Mudd
- **NIAAA:** Bob Freeman
- **NIMH (UG3/UH3 only):** Christine Ulbricht
- **NIDA (UG3/UH3 only):** Barbara Oudekerk
- **ODP:** Jennifer Alvidrez
- **SGMRO:** Christopher Barnhart
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See Financial/Grants Management
contacts in the PARs.



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Part IV:

Participant Questions

Submit questions via Q and A button



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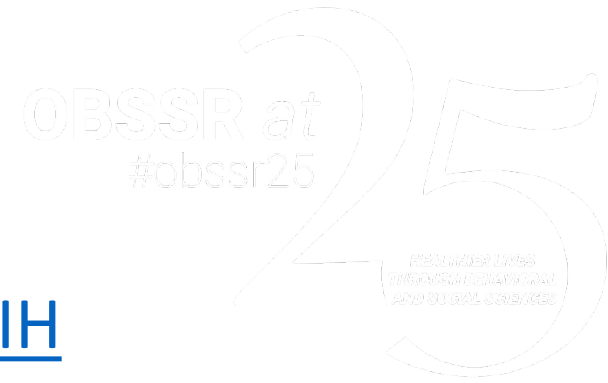
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