Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases Extramural Research Program Office

Modeling Infectious Diseases in Healthcare Research Projects to Improve Prevention Research and Healthcare Delivery (MInD Healthcare)

RFA-CK-20-003

Application Due Date: 02/18/2020

Modeling Infectious Diseases in Healthcare Research Projects to Improve Prevention Research and Healthcare Delivery (MInD Healthcare)

RFA-CK-20-003

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Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Emerging and Zoonotic Infectious Diseases

Notice of Funding Opportunity (NOFO) Title

Modeling Infectious Diseases in Healthcare Research Projects to Improve Prevention Research and Healthcare Delivery (MInD Healthcare)

Activity Code

U01 – Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-CK-20-003

Assistance Listings (CFDA) Number(s)

93.084

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support innovative research to develop and apply computational tools and mathematical methods for: 1) modeling the spread of pathogens that cause healthcare-associated infections (HAIs) and related antimicrobial resistant (AR) infections; 2) predicting outbreaks of HAI pathogens and trends in the burden of antimicrobial resistant and susceptible HAIs; and 3) investigating the effectiveness of intervention strategies. The models should be developed with the intent that they will be tools for researchers, policymakers, or public health workers who want to better understand and respond to HAIs in the United States. This NOFO will also create a network of leaders in the fields of HAI and AR modeling that will be a resource for informing the development of relevant evidence-based policy. MInD-Healthcare will provide a network of leading modelers to respond to evolving public health needs and emergencies in healthcare settings.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-CK-20-003, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**12/18/2019**
Application Due Date:	**02/18/2020**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:	**04/02/2020**
Secondary Review:	**04/23/2020**
Estimated Start Date:	**08/01/2020**
Expiration Date:	**02/19/2020**
Due Dates for E.O. 12372:	**Due no later than 60 days after the application receipt date.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 15 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

- **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to support innovative research to develop and apply computational tools and mathematical methods for: 1) modeling the spread of healthcare-associated infections (HAIs) and related antimicrobial resistant (AR) infections; 2) predicting HAI outbreaks and trends in the burden of antimicrobial resistant and susceptible HAIs; and 3) investigating the potential effectiveness of a wide variety of intervention strategies. The models should be useful to researchers, policymakers, and public health workers who want to better understand and respond to HAIs and AR infections in the United States. This NOFO will also create a network of leaders in the fields of HAI and AR modeling that will be a resource for informing the development of relevant evidence-based policy. Additionally, MInD-Healthcare will provide a network of experienced modelers to respond to evolving public health needs and emergencies.
- **Mechanism of Support:** U01 - Research Project - Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is $11,000,000 to $13,000,000. It is anticipated that up to four (4) awards will be made.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $2,200,000 to $2,600,000 with individual awards estimated to range from $550,000 to $650,000. The estimated total funding (direct and indirect) for the entire project period for all awards is $11,000,000 to $13,000,000. The project period is anticipated to run from 08/01/2020 to 07/31/2025.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. **NOTE:** CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include multiple PDs/PIs, and if so, must include a Leadership Plan that describes the roles, responsibilities, and the working relationship of the identified PD/PIs. Only one PD/PI may be the primary CDC contact for the award, and this must be clearly indicated in the application.
- **Number of Applications.** Only one application per institution (normally identified by

having a unique DUNS number) is allowed.

- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form E is to be used when completing the application package.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Sections 301(a) [42 USC 241(a)], 307 [42 USC 242*l*], and 317(k)(2) [42 USC 247b(k)(2)], as amended.

1. Background and Purpose

Healthcare associated infections (HAIs) are associated with substantial morbidity and mortality (Magill, *et al. NEJM* 2014). Antimicrobial resistant (AR) strains of HAI pathogens are more common and becoming a significant public health threat, including strains that are resistant to antibiotics used as treatments of last resort (CDC 2013). Better understanding of the dynamics of HAI pathogen transmission, within and between U.S. healthcare facilities and in the community, is an important prerequisite to implementing optimal evidence-based prevention strategies. However, HAI pathogen transmission is complex, often involving transmission between multiple human actors (e.g., healthcare workers, hospital patients, nursing home residents) and non-human actors (e.g., the environment, reusable medical equipment). The most affected groups are frequently sick, vulnerable populations, which present challenges in studying the transmission process. There are also large numbers of intervention combinations that could potentially be evaluated, but limited resources preclude their testing across all healthcare settings (e.g., acute care hospitals, long-term acute care hospitals, nursing homes).

Modeling of HAI pathogen transmission and AR transmission creates a virtual laboratory in which researchers are able to investigate drivers of disease spread and estimate the relative benefits of multiple prevention strategies in a timely and cost-effective manner. For example, epidemiological modeling has and will continue to provide insights into how HAI pathogens spread through healthcare settings and the community geospatially, temporally, and through patient transfer and social networks (Lee, *et al*. *Am J Pub Health* 2011, Slayton *et al. MMWR* 2015). Modeling can enable a better understanding of the dynamics of pathogen spread and identify which interventions can maximize prevention and control. The latter includes pathogen-specific response strategies and intervention bundles which could be effective across a range of organisms (Paul *et al. Clin Infect Dis* 2019). Epidemiologic modeling can be used to enhance the understanding of findings from previous epidemiologic trials, and aid in the design of future epidemiologic trials (Harris *et al. J Hosp Infect* 2017, Halloran *et al. BMC Med* 2017, Bellan *et al. Lancent Infect Dis* 2015). Individual and social behavior contributes greatly to the dynamics of infectious disease emergence and spread as well as to compliance with public health policies. Modeling can help assess the potential impact of behavioral interventions.

The purpose of this Notice of Funding Opportunity (NOFO) is to support innovative transmission modeling research to expand knowledge and develop tools to better understand the spread of healthcare-associated infections, particularly those that are resistant to antimicrobials, and

identify promising combinations of interventions for preventing the spread of HAI pathogens. This includes the creation of a network of multidisciplinary scientists conducting computational, statistical, and mathematical research to improve the ability to prepare for, detect, control, and prevent the growing problem of antimicrobial resistant HAI pathogens in the United States. This network will be called the Modeling Infectious Diseases in Healthcare Network (MInD-Healthcare Network).

References

1. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Available at: http://www.cdc.gov/drugresistance/threat-report-2013/index.html
2. Lee BY, McGlone SM, Song Y, Avery TR, Eubank S, Chang CC, *et al*. Social network analysis of patient sharing among hospitals in Orange County, California. *Am J Public Health.* 2011 Apr;101(4):707-13.
3. Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA, *et al*. Multistate point-prevalence survey of health care-associated infections. *N Engl J Med.* 2014 Jun 26;370(26):2542-3.
4. Slayton RB, Toth D, Lee BY, Tanner W, Bartsch SM, *et al*. Vital Signs: Estimated Effects of a Coordinated Approach for Action to Reduce Antibiotic-Resistant Infections in Health Care Facilities - United States. *MMWR Morb Mortal Wkly Rep*. 2015 Aug 7;64(30):826-31.
5. Paul P, Slayton RB, Kallen AJ, Walters MS, and Jernigan JA. Modeling regional transmission and containment of a healthcare-associated multidrug-resistant organism. *Clin Infect Dis,* 2019 Mar 28. Pii: ciz248. Epub ahead of print.
6. Harris AD, Morgan DJ, Pineles L, Perencevich EN, and Barnes SL. Deconstructing the relative benefits of a universal glove and gown intervention on MRSA acquisition. *J Hosp Infect.* 2017 May;96(1):49-53.
7. Halloran ME, Auranen K, Baird S, Basta NE, Bellan SE, *et al.* Simulations for designing and interpreting intervention trials in infectious diseases. *BMC Med.* 2017 Dec 29;15(1):223.
8. Bellan SE, Pulliam JR, Pearson CA, Champredon D, Fox SJ, *et al.* Statistical power and validity of Ebola vaccine trials in Sierra Leone: a simulation study of trial design and analysis. *Lancet Infect Dis*. 2015 Jun;15(6):703-10.

Healthy People 2020 and other National Strategic Priorities

Healthy People 2020:

1. Healthy People 2020: Prevent, reduce, and ultimately eliminate healthcare-associated infections (HAIs): https://www.healthypeople.gov/2020/topics-objectives/topic/healthcare-associated-infections
2. CDC Strategic Framework: Ending Epidemics: Antimicrobial Resistance: https://www.cdc.gov/about/organization/strategic-framework/index.html
3. National Strategy for Combating Antibiotic Resistant Bacteria: https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html

Goal 1: Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections.

- 1.1 Implement public health programs and reporting policies that advance antibiotic-resistance prevention and foster antibiotic stewardship in healthcare settings and the community.

Goal 2: Strengthen National One-health Surveillance Efforts to Combat Resistance.

- 2.2 Expand and strengthen the national infrastructure for public health surveillance and data reporting and provide incentives for timely reporting of antibiotic-resistance and antibiotic use in all healthcare settings.

Goal 3: Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria.

• 3.1 Develop and validate new diagnostics -- including tests that rapidly distinguish between viral and bacterial pathogens and tests that detect antibiotic-resistance – that can be implemented easily in a wide range of settings.

• 3.2 Expand availability and use of diagnostics to improve treatment of antibiotic-resistant infections, enhance infection control and facilitate outbreak detection and response in healthcare and community settings.

Goal 4: Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines

- 4.1 Conduct research to enhance understanding of ecological determinants and environmental factors that facilitate the development of antibiotic resistance and the spread of resistance genes that are common to animals and humans.
- 4.2 Increase research focused on understanding the nature of microbial communities, how antibiotics affect them, and how they can be harnessed to prevent disease.
- 4.4 Develop non-traditional therapeutics and innovative strategies to minimize the effects of resistant bacteria in human and animal populations.

HHS Priority Goals: https://www.hhs.gov/about/strategic-plan/index.html

- Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System.
    - Strategic Objective 1.2: Expand safe, high-quality healthcare options, and encourage innovation and competition.
- Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play.
    - Strategic Objective 2.2: Prevent, treat, and control communicable diseases and chronic conditions.
- Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences.
    - Strategic Objective 4.1: Improve surveillance, epidemiology, and laboratory services.
    - Strategic Objective 4.2: Expand the capacity of the scientific workforce and infrastructure to support innovative research.

National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination https://health.gov/hcq/prevent-hai-action-plan.asp

This NOFO aligns with these strategic priorities by funding research that will elucidate the drivers of AR and HAI pathogen transmission and identify which bundles of interventions are most effective at reducing the related burden of disease. These results can be used to inform clinical practice and inform the development of health policy.

Public Health Impact

Prevention of healthcare-associated infections (HAIs) is a focus of the Department of Health and Human Services Healthy People 2020, CDC's Strategic Framework, and the National Strategy for Combating Antibiotic Resistant Bacteria. This NOFO should contribute to HAI prevention by supporting innovative transmission modeling research to: a) improve the understanding of major determinants of HAI pathogen transmission, particularly for those strains that are resistant to antimicrobials, and b) identify promising combinations of interventions for preventing the spread of HAI pathogens. The knowledge and prevention gains resulting from this work should reduce the morbidity, mortality, and costs associated with HAI pathogens. Furthermore, the results obtained from the network of leading HAI modelers created by this NOFO will provide information to assist CDC in developing evidence-based guidelines and improving public health across the United States.

Relevant Work

1. National Strategy for Combating Antibiotic Resistant Bacteria: https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html
2. Biggest Threats and Data: https://www.cdc.gov/drugresistance/biggest_threats.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdrugresistance%2Fthreat-report-2013%2Findex.html
3. United States Department of Health and Human Services, National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination: https://health.gov/hcq/prevent-hai.asp

Abbreviated list of HAI and antimicrobial resistance modeling publications:

1. Austin DJ and Anderson RM. Studies of antibiotic resistance within the patient, hospitals and the community using simple mathematical models. *Philos Trans R Soc Lond B Biol Sci. 1999* Apr 29;354(1384):721-38.
2. Campbell F, Cori A, Ferguson N, and Jombart T. Bayesian inference of transmission chains using timing of symptoms, pathogen genomes and contact data. *PLoS Comput Biol*. 2019 Mar 29;15(3): e1006930.
3. Campbell F, Strang C, Ferguson N, Cori A, and Jombart T. When are pathogen genome sequences informative of transmission events? *PLoS Pathog.* 2018 Feb 8;14(2): e1006885.
4. Chang HH, Dordel J, Donker T, Worby CJ, Feil EJ, *et al.* Identifying the effect of patient sharing on between-hospital genetic differentiation of methicillin-resistant *Staphylococcus aureus*. *Genome Med* 2016 Feb 13;8(1):18.
5. Donker T, Wallinga J, and Grundmann H. Patient referral patterns and the spread of

hospital-acquired infections through national health care networks. *PLoS Comput Biol.* 2010 Mar 19;6(3): e1000715.
6. Eyre DW, Davies KA, Davis G, Fawley WN, Dingle KE, *et al.* Two distinct patterns of *Clostridium difficile* diversity across Europe indicating contrasting routes of spread. *Clin Infect Dis*. 2018 Sep 14;67(7):1035-1044.
7. Grimm V, Berger U, DeAngelis D, Polhill JG, Giske J, Railsback S. The ODD protocol: A review and first update. *Ecological modelling.* 2010;221(23):2760-8.
8. Khader K, Thomas A, Huskins WC, Leecaster M, Zhang Y, *et al.* A Dynamic Transmission Model to Evaluate the Effectiveness of Infection Control Strategies. *Open Forum Infect Dis.* 2017 Feb 10;4(1):ofw247.
9. Lee BY, Bartsch SM, Hayden MK, Welling J, DePasse JV, *et al.* How Introducing a Registry With Automated Alerts for Carbapenem-resistant Enterobacteriaceae (CRE) May Help Control CRE Spread in a Region. *Clin Infect Dis.* 2019 May 9
10. Paul P, Slayton RB, Kallen AJ, Walters MS, Jernigan JA. Modeling regional transmission and containment of a healthcare-associated multidrug-resistant organism. *Clin Infect Dis.* 2019 Mar 28.
11. Sewell DK, Simmering JE, Justice S, Pemmaraju SV, Segre AM, Polgreen PM. Estimating the Attributable Disease Burden and Effects of Interhospital Patient Sharing on *Clostridium difficile* Infections. *Infect Control Hosp Epidemiol*. 2019 Jun;40(6):656-661.
12. Smith DL, Dushoff J, Perencevich EN, Harris AD, and Levin SA. Persistent colonization and the spread of antibiotic resistance in nosocomial pathogens: resistance is a regional problem. *Proc Natl Acad Sci U S A*. 2004 Mar 9;101(10):3709-14.
13. Slayton RB, Scott RD, Baggs J, Lessa FC, McDonald LC, and Jernigan JA. The cost-benefit of federal investment in preventing *Clostridium difficile* infections through the use of a multifaceted infection control and antimicrobial stewardship program. *Infect Control Hosp Epidemiol.* 2015 Jun;36(6):681-7.
14. Smith DL, Levin SA, and Laxminarayan R. Strategic interactions in multi-institutional epidemics of antibiotic resistance. *Proc Natl Acad Sci USA.* 2005 Feb 22;102(8):3153-8.
15. Tedijanto C, Olesen SW, Grad YH, Lipsitch M. Estimating the proportion of bystander selection for antibiotic resistance among potentially pathogenic bacterial flora. *Proc Natl Acad Sci USA.* 2018 Dec 18;115(51): e11988-e11995.
16. Thomas A, Khader K, Redd A, Leecaster M, Zhang Y, *et al.* Extended models for nosocomial infection: parameter estimation and model selection. *Math Med Biol*. 2018 Mar 16;35(suppl_1):29-49.
17. Toth DJA, Khader K, Slayton RB, Kallen AJ, Gundlapalli AV, *et al.* The potential for interventions in a long-term acute care hospital to reduce transmission of carbapenem-resistant enterobacteriaceae in affiliated healthcare facilities. *Clin Infect Dis.* 2017 Aug 15;65(4):581-587.
18. Van Kleef E, Luangasanatip N, Bonten MJ, and Cooper BS. Why sensitive bacteria are resistant to hospital infection control. *Wellcome Open Res.* 2017 Mar 10; 2:16.

2. Approach

For the purposes of this NOFO, "transmission modeling" is defined as statistical, computational, and mathematical methods employed to study the spread of infectious diseases that account for transmission from infectious to susceptible individuals. Examples of transmission modeling include, but are not limited to, computational and mathematical methods to simulate the spread of

infectious diseases (e.g., compartmental models, agent-based models, network models) and statistical methods to quantify the transmissibility of a pathogen (e.g., estimate reproduction numbers, describe contacts between people relevant to transmission, and conduct phylodynamic analyses).

In order for modeling results to be appropriately used, it is essential that decision-makers understand the limitations of the data and methods used, the assumptions employed, and how these issues affect the results (i.e., through complete model specification of compartmental models or through the use of a modified Overview, Design concepts, and Details [ODD] framework for describing agent-based or individual-based models). Consequently, uncertainty analyses, sensitivity analyses, and model validation, and their clear communication, are critical steps in the modeling process. Such analyses are especially important when there are little or no data to support specific assumptions or parameters.

Uncertainty analyses can be defined as summarizing the range of possible outcomes (e.g., numbers of cases averted) due to imperfect knowledge regarding the true model structure (e.g., natural history of disease, demographics relevant to transmission and disease, risk factors) and parameter values corresponding to the real world. Sensitivity analyses can be defined as quantifying which parameters or aspects of the model structure have the greatest influence on a model's outcomes. Model validation can be defined as a comparison of model outputs to data not used in the construction of the model to help ensure that the model performs as expected. Stochastic process can be defined as a family of random variables indexed against some other variable or a set of variables.

Awardees will use existing or simulated datasets, as well as real-time information, to conduct analyses and build computational models relevant to the goals of the MInD-Healthcare Network. Funding from this award may be used for the generation of simulations. Any anticipated need for primary data collection to directly inform model calibration or validation throughout the five (5)-year project period should be outlined in the initial research plan of the application and should not exceed 25% of the proposed annual budget.

Objectives/Outcomes

Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

The Research Objectives are to develop and/or apply computational, statistical, and/or mathematical transmission modeling methods to improve the understanding of major determinants of transmission and/or prevention of one or more healthcare-associated infections, particularly antimicrobial resistant infections. HAIs with substantial burden and/or clinical significance include, but are not limited to:

- *Candida auris*: An emerging fungus first identified in 2009 in Japan that presents a serious global health threat. *C. auris* often does not respond to commonly used antifungal drugs, making infections difficult to treat.
- *Clostridioides difficile*: Responsible for almost half a million infections and estimated to be associated with approximately 29,000 deaths in the United States annually.
- Enterobacteriaceae: Enterobacteriaceae with notable resistance mechanisms, such as Extended Spectrum β-Lactamase (ESBL) Producing-Enterobacteriaceae and Carbapenem-

Resistant Enterobacteriaceae (CRE), are of special concern because they can be particularly challenging to treat.

- Resistant *Acinetobacter* species: Outbreaks of *Acinetobacter* infections typically occur in intensive care units and healthcare settings housing very ill patients. *Acinetobacter* infections rarely occur outside of healthcare settings. More than 60% of *Acinetobacter* infections are resistant to at least three classes of antibiotics.
- Resistant *Pseudomonas aeruginosa*: Infections with *P. aeruginosa* are caused by strains of bacteria found widely in the environment.
- *Staphylococcus aureus*: *S. aureus*, including strains with notable resistance mechanisms such as methicillin-resistant *S. aureus* (MRSA), vancomycin-intermediate *S. aureus* (VISA), and vancomycin-resistant *S. aureus* (VRSA), are of special concern because they can be challenging to treat.

Healthcare-associated infections also include those prioritized in the Health and Human Services Action Plan to Prevent Healthcare-Associated Infections (e.g., device and procedure-associated infections, multi-drug resistant organisms, viruses, and other pathogens). For more information on the HHS Action Plan and the National Strategy for Combating Antibiotic Resistant Bacteria, visit the following websites:

https://health.gov/hcq/prevent-hai-action-plan.asp

https://www.cdc.gov/drugresistance/us-activities/national-strategy.html

The anticipated outcomes of the proposed research should result in evidence that allows clinicians, public health officials, and/or policymakers to:

a. Gain a significantly better understanding of the burden of HAI pathogens;
b. Identify new risk factors and mechanisms for the spread of HAI pathogens;
c. Rank and prioritize the delivery of specific interventions that are most effective in combating HAIs and/or antimicrobial resistant HAIs;
d. Identify high priority research questions relevant to estimating the burden of disease, identifying key risk factors for transmission, determining if there are groups of people that have a disproportionate role in transmission, and/or intervening effectively to eliminate HAIs; and
e. Build HAI and antimicrobial resistant HAI modeling capacity for responding to emerging public health threats.

Examples of thematic research areas for HAI transmission modeling are outlined below. Applications should cover at least two of these areas, including at least one from Section A and one from Section B. Applications may propose to address one or more of the thematic areas from each Section. However, it is not required that applications address more than one of the activities in a given Section. Sections should be clearly indicated in the application using the bolded headings below.

Section A: **Core Activities**

Antimicrobial Resistance: Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics. Such cases can cause even greater concern

than antimicrobial susceptible infections because effective treatment may be delayed, leading to increased morbidity, mortality, and economic costs. Modeling can contribute to understanding: a) the evolution, sources, and spread of resistance in microbial populations, b) the dynamics of pathogen spread at the hospital, public health system, and regional levels, c) the patterns of antimicrobial use that have the largest impact on the dissemination of antimicrobial resistant strains, and d) the interplay between susceptible and resistant strains. Modeling can also help evaluate evidence regarding differences in transmission patterns of resistant and susceptible strains, and the effectiveness of particular interventions to reduce the incidence of antimicrobial resistant infections. This includes, but is not limited to: antimicrobial stewardship, use of rapid tests to identify pathogens and their antimicrobial susceptibility, screening and isolation of carriers and cases, hand hygiene and barrier precautions, interventions to reduce patient shedding of resistant organisms, and other interventions.

Connectedness of Patients Within and/or Among Healthcare Facilities: Pathogens that cause HAIs, and AR pathogens in particular, can be acquired anywhere healthcare is delivered, including inpatient acute care hospitals (e.g., short stay hospitals, long-term acute care hospitals), outpatient settings (e.g., clinics, ambulatory surgical centers, end-stage renal disease facilities), and long-term care facilities (e.g., skilled nursing facilities and rehabilitation centers). In the process of receiving healthcare, patients may have interactions with other patients, healthcare workers, and the environment that could potentially result in transmission of infectious diseases. Application of the principles of network analysis both within and among healthcare facilities can contribute to understanding how the movement of healthcare workers and patients, and their interactions with the healthcare environment, affect HAI pathogen transmission dynamics and represent barriers to, and opportunities for, disease prevention. Such research should provide actionable information to help improve decision-making at the levels of federal, state, or local health departments as well as within individual healthcare facilities.

Surveillance: The effectiveness of public health interventions can be improved if accurate estimates of the overall incidence and burden of disease, high-risk groups, primary modes of transmission and transmission settings are known. Burden of disease estimates also assist in setting public health priorities and gauging progress in the control of nosocomial pathogens. Consequently, accurate and efficient surveillance systems are crucial to combating the spread of HAI pathogens and antimicrobial resistant pathogens. Modeling can help identify efficient strategies for estimating the incidence or prevalence of carriage and the disease burden of established pathogens. The early identification and accurate threat assessment of emerging nosocomial infections, including, but not limited to, their transmissibility, case-fatality rates, average numbers of transmissions and infections that occur for each clinical case identified, is important.

Section B: **Focus Areas**

Economic Modeling: Understanding potential changes in disease dynamics, with prevention strategies that are developed under realistic economic constraints, is vital for designing feasible prevention strategies. Estimating the costs and epidemiologic benefits of pathogen-specific or more general response strategies and intervention bundles can contribute to decision-making around implementation of prevention strategies. Modeling the development and implementation of incentives and penalties from both private and public healthcare payers can also provide

important policy insights. Assessing the burden and cost of intervention strategies can aid in their design and implementation (e.g., adverse outcomes related to inappropriate outpatient antibiotic use and the potential impact of improving antibiotic use may be useful for strengthening the case for antibiotic stewardship in ambulatory healthcare settings, transmission-based precautions, etc.).

Genomics: Genetic sequences can provide highly detailed information on pathogen relatedness, which can be used to inform transmission inferences when combined with traditional epidemiologic data (e.g., demographics, common exposures, dates, and locations of patients sampled). Combining these data sources can permit better characterization of the spread of pathogens across timescales and multiple geographic levels (e.g., within hospitals, across state and other borders). This information can improve our understanding of disease dynamics including, but not limited to: how patient and healthcare worker movement patterns affect disease transmission, improving the understanding of patient and environmental factors that affect the risk of transmitting or acquiring HAI and related pathogens, quantifying the amount of transmission across settings (e.g., short-term acute care hospitals, long-term acute care hospitals, nursing homes, wider community), which may not accurately reflect where disease diagnoses occur, and the role of endogenous versus exogenous routes of transmission. Additionally, this information can inform: defining cutoffs for using sequencing analyses to determine which cases are part of an outbreak and are likely associated with a particular transmission pathway; where interventions should be targeted to interrupt transmission; the evolution and emergence of strains of interest (e.g., antimicrobial resistant strains, hypervirulent strains), including how such information can be used to better understand and reduce HAI pathogen transmission; the fraction of total pathogen transmission that occurs from asymptomatically colonized versus sick individuals; the amount of transmission that occurs due to long-lasting environmental contamination (e.g., hospital transmission that occurs after an infectious patient has been discharged due to contamination of rooms or equipment); and calculation of parameters useful for simulations (e.g., generation times, serial intervals, reproduction numbers). Sequence data from CDC surveillance systems and outbreak investigations can be found at https://www.ncbi.nlm.nih.gov/bioproject/531911.

Nursing Homes: Over four million Americans are admitted to, or reside in, nursing homes and skilled nursing facilities each year and one to three million serious infections occur every year in these facilities. Recent data suggests that prevalence of AR pathogen colonization is very high in these settings, and that transmission in such facilities may play an important role in amplifying and sustaining regional spread of multi-drug resistant organisms (MDROs). This area focuses on understanding the transmission dynamics within facilities across the post-acute care spectrum; in particular, high-acuity skilled nursing facilities providing ventilator services, as well as the role of nursing homes in the broader transmission dynamics across regions.

Outbreak Response: A critical step in responding to an outbreak is the ability to correctly identify and characterize it. In some cases, the speed and accuracy of a response (e.g., provision of antimicrobials, contact tracing, isolation, etc.) may determine whether an outbreak will be contained. Technological advances in disease detection will continue to provide considerable data, and statistical and modeling methods are needed to search for, and characterize, signals that reliably identify outbreaks in a timely manner in the presence of highly variable background information. These issues are relevant at many levels of organization, from individual hospitals, to communities, metropolitan areas, and countries. Additionally, modeling can help continually refine approaches for limiting the spread of new or rare forms of antibiotic resistance by detecting

threats early and with sufficient specificity (e.g., regional prevention strategies, https://www.cdc.gov/hai/containment/index.html).

Simulations of Epidemiologic Studies: Healthcare-associated infections are difficult to study using standard epidemiologic methods. For example, colonization often does not lead to clinical symptoms and therefore is not captured in electronic health records or standard surveillance systems, making it difficult to identify risk factors for transmission or acquisition of HAI pathogens. There can also be strong confounding (e.g., case-fatality rates can be biased because very ill people are susceptible to acquiring an HAI pathogen and already have an elevated risk of death) and selection bias (e.g., healthier people are discharged from the hospital more quickly than very ill people, thereby reducing their risk of acquiring an HAI pathogen and potentially creating informative censoring; health status could also affect the duration of colonization and/or the risk of progressing to disease; durations of colonization can be both left-censored and right-censored). Simulations can be used to investigate alternative ways for designing data collection and/or conducting analyses with goals that include, but are not limited to, obtaining more reliable estimates of risk factors for colonization and/or infection, case-fatality rates, effectiveness of individual-level, facility-level and/or regional interventions, fraction of total transmission due to environmental contamination versus transmission via healthcare workers versus direct patient-to-patient contact, the fraction of transmission that occurs from asymptomatically colonized versus symptomatic individuals, estimating unintended consequences of intervention strategies, incubation periods, generation times, ability to identify the appropriate model structure for a pathogen's transmission and accurately estimate relevant model parameter values, and other summary measures of interest.

Systems Approaches: Systems approaches can be useful in optimizing the implementation of prevention programs and interventions on the dynamics of antimicrobial resistance and healthcare-associated infections. A systems approach (e.g., using an operations research approach) aims to identify factors which are likely to give rise to human error and subsequently modify the underlying systems of care to reduce the occurrence of errors or minimize their impact on patients. Utilizing a systems approach necessitates attention to human factors engineering including, but not limited to, the design of protocols, checklists, and schedules.

Zoonotics: Although the focus of this announcement is healthcare-associated human disease, animals can act as reservoirs, hosts and vectors of infectious agents for humans. For example, animals could serve as a source of novel strains of antibiotic resistant bacteria and other pathogens that often cause healthcare-associated infections. Studies of animal populations should focus on issues or modeling approaches directly relevant to the colonization and/or infection of people beyond those working in the agriculture industry, or who live in areas where large-scale agricultural production is common. Examples of relevant research include, but are not limited to, analyses of genetic data to assess the role of transmission from animals to humans in the emergence of novel strains of HAI pathogens that spread widely among humans.

Target Population

Research activities proposed under this NOFO should target populations at risk for healthcare-associated infections in the United States including, but not limited to, patients admitted to hospitals and long-term care facilities, as well as patients receiving care in ambulatory settings. Applications could also assess the community transmission of pathogens that are typically associated with healthcare-associated infections where there is evidence that such community

transmission causes a substantial fraction of: a) the burden of severe disease (e.g., hospitalization, intensive care unit admission, death) and/or b) antibiotic resistant HAI pathogens in healthcare settings, and/or c) disease onsets while in healthcare settings for the HAI pathogens considered. Applications should focus on transmission settings relevant to the United States.

Collaboration/Partnerships

Awardees of this NOFO will be organized into a network. Principal Investigators from each recipient institution will act as network representatives on the Steering Committee. The Steering Committee will work collaboratively to serve in an advisory role to individual investigators, as needed. A well-developed Steering Committee is integral to the program's success but will not serve as an advisory committee to CDC.

Participation in the MInD Healthcare Network includes, but is not limited to, active participation in conference calls, webinars, in-person meetings (i.e., grantee meetings and special projects meetings) and collaborative modeling exercises to facilitate multicenter collaboration and the achievement of the NOFO's aims. In addition, the MInD-Healthcare network will collaborate to respond to public health emergencies utilizing computational, statistical, and/or mathematical transmission modeling methods.

Applications should describe previous successful collaborations among institutions. In addition, applications should describe both capacity and willingness to collaborate with other selected MInD-Healthcare grantees. Applications should describe plans for recipients to participate in at least one collaborative project with at least one other recipient.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a five (5)-year research project period. Investigators will establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application's project plan and describe the development and implementation of project performance measures based on specific programmatic objectives.

Reports summarizing the progress and short-term outcomes of each project will be submitted, at a minimum, on an annual basis. Investigators should outline an evaluation plan in the application. Performance measures may include:

- Progress toward completion of proposed research projects that can be feasibly completed within the five (5)-year project period (e.g., employing a Gantt chart).
- Development of peer-reviewed articles that report on proposed research projects.
- Presentation of findings as a result of the proposed research project at meetings and conferences.
- Complete methodological descriptions for each model if agent-based or individual-based models are developed using a modified Overview, Design concepts, and Details (ODD) protocol.
- The number of manuscripts documenting models and applications applicable as a result of the work from the NOFO.
- Descriptions of communication products and data visualizations appropriate for federal

and state public health officials.

Translation Plan

The anticipated outcome of the proposed research should result in evidence that informs clinicians, public health officials, and/or policymakers when ranking and prioritizing the delivery of specific interventions that are effective in combating healthcare-associated infections and antimicrobial resistance and/or the development of new data collection studies that will gather data that are critical to effectively identifying the burden of disease, risk factors for transmission, and/or intervening effectively to eliminate healthcare-associated infections. Code developed as a part of this research should be sharable and run on commonly available platforms, preferably non-proprietary platforms, consistent with the federal government source code policy (https://sourcecode.cio.gov/).

Applications will provide a plan for presentation of research findings at appropriate scientific meetings and for publication in peer-reviewed literature. In addition, relevant findings will be made available to inform policy makers, State and local public health partners, and, as appropriate, to State and federal advisory committees, including the Healthcare Infection Control Practices Advisory Committee, and other entities, and professional organizations that produce recommendations for HAI prevention to inform decision-making.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $13,000,000

Estimated Total Annual Budget Period Funding:

Year 1: $2,600,000

Year 2: $2,600,000

Year 3: $2,600,000

Year 4: $2,600,000

Year 5: $2,600,000

Estimated total funding available for first year (first 12 months), including direct and

indirect costs: $2,600,000

Estimated total funding available for entire project period, including direct and indirect costs: $13,000,000

Anticipated Number of Awards: 4

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:	$650,000 Per Budget Period
Award Floor:	$550,000 Per Budget Period
Total Period of Performance Length:	5 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

2. Foreign Organizations

Foreign Organizations are eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm DUNS by sending an e-mail to ccrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf.

Foreign components of U.S. Organizations are eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

- Private non-profit institutions of higher education
- Non-profits (Other than Institutions of Higher Education)
- Faith-based or Community-based Organizations
- Regional Organizations
- Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with

"Other Attachment Forms" when submitting via www.grants.gov.

- Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to
- https://gov.ecfr.io/cgi-bin/searchECFR?ob=r&;idno=&;q1=FFRDC&;r=&;SID=1510a9feb7999d185d40b026ad998cc0&;mc=true

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Non-profit Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications requesting over $650,000 for the first 12-month budget period will be considered non-responsive.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least

30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for

HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by

selecting the Add Optional Form button in the left navigation panel.

Letters of Support from partner companies or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Please include all of the eight (8) mandatory forms listed below in the application package:

Mandatory

1. SF424(R&R)[V2.0];
2. PHS 398 Cover Page Supplement [V4.0];
3. Research and Related Other Project Information [V1.4];
4. Project/Performance Site Location(s) [V2.0];
5. Research and Related Senior/Key Person Profile (Expanded) [V2.0];
6. Research and Related Budget [V1.4];
7. PHS 398 Research Plan [V4.0];
8. PHS Human Subjects and Clinical Trials Information [V1.0].

Please include the one (1) optional form listed below, if applicable, in the application package:

Optional

1. R&R Subaward Budget Attachment(s) Form 5 YR 30 ATT.

3. Letter of Intent

Due Date for Letter of Intent: **12/18/2019**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. "Overview Information" and immediately above, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant institution

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this Notice of Funding Opportunity (NOFO)

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS US8-1

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.

4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

NOTE: The **Research Strategy** should be organized under 3 headings: Significance, Innovation and Approach. Under the "Approach" heading, describe the proposed research plan, including staffing, timeline (e.g., Gantt chart), and potential risk and risk mitigation strategies (e.g., primary data collection is needed only for model validation).

In both the **Research Strategy** and in the **Project Summary/ Abstract (Description)** of the application, the model structures or model elements and methodological approaches should be clearly described. Also, in both of these sections of the application, the geographic representation of the dataset(s) proposed should be clearly defined.

Letters of Support from partner companies or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PLEASE NOTE all page limitations in this NOFO. Pages over the limit will be removed and not peer reviewed, possibly negatively impacting the overall impact score and funding.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 15 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system. **CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide** https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they

have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/18/2020**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (http://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Additional Funding Restrictions:

1. Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.
2. Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.
3. Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).
4. On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of US Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.
5. Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this NOFO (https://www.cdc.gov/grants/additionalrequirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.
6. Applications submitted under this notice of funding opportunity must not include

activities that overlap with simultaneously-funded research under other awards.

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent,

whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Please note the new requirement for a **Risk Assessment Questionnaire** (described above) that should be uploaded as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application.

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf

- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? 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?

- Is there a strong scientific premise for the project?
- Does the work address a scientific problem of great importance to public health research and/or practice?
- What is the potential impact of the research on public health in the US and/or globally?
- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach and how will this improve and be of value to public health?
- Does the proposed work have the potential to improve the quality of healthcare delivery and/or public health practice or improve patient safety?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? 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?

- If in the early stages of independent careers, do the investigators have appropriate experience and training? If established, have the investigators demonstrated an ongoing record of accomplishment that has advanced their field(s)?
- Does the PI have expertise in infectious disease transmission modeling as evidenced by a significant track record of high-quality peer reviewed publications?
- Does the research team have expertise in the dynamics of healthcare-associated infections, antimicrobial resistance, and/or methodological expertise that is relevant and scientifically appropriate for addressing the prevention of healthcare-associated infections or related antimicrobial resistance?
- Does the research team have relevant epidemiologic, clinical, and modeling expertise sufficient to define modeling questions, generate hypotheses, conduct literature reviews, determine needed data inputs, and construct models in collaboration with other awardees?
- Do the co-investigators have a track record of successful collaborations evidenced by letters of support and/or shared authorship on scientific publications?
- Do the investigators have a track record of working effectively with local, state, federal, or international organizations to address public health problems evidenced by letters of support and/or shared authorship on scientific publications?
- Did previous research provide high quality outputs and contribute to improvements in public health practice and population health, as evidenced by a strong history of peer reviewed publications?

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?

- Does the application challenge and seek to shift current public health paradigms or approaches?
- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC and/or public health?
- Is the scope of the proposed modeling activity (e.g., represented population(s), types of healthcare facilities included, number or type of interventions and risk factors examined, or molecular characterization) innovative?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? 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?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Does the Approach section clearly indicate which thematic areas from Sections A and B are included in the application?
- Does the application include development and application of transmission model(s) with significant advantages in terms of scope or type of questions that can be appropriately addressed compared to existing models?
- Do the proposed aims build upon the published literature, directly and/or indirectly?
- Does the application describe if and how the modeling approach(es) account for population, disease, and intervention characteristics?
- Does the application describe complete model descriptions (e.g., using a modified Overview, Design concepts, and Details (ODD) protocol), if agent-based or individual-based models are developed?
- Does the application demonstrate an understanding of the mechanism(s) by which interventions act to interrupt pathogen transmission or provide a strong rationale for identifying the influence of gaps in the current knowledge base?
- Are examples of previous public health response activities and/or special projects aimed at rapidly tackling high-priority public health questions described in the application?
- Does the application demonstrate the ability to share mathematical modeling approaches, assumptions, and inputs and compare results with other recipients and CDC?
- Does the application clearly describe methodological approaches for transmission modeling to include, but not limited to, computational and mathematical methods to simulate the spread of infectious diseases (e.g., compartmental models, agent-based models, network models) and methodological approaches for statistical methods to quantify the transmissibility of a pathogen (e.g., estimate reproduction numbers, describe contacts between people relevant to transmission, and conduct phylodynamic analyses)?
- Does the application address CDC public health priorities and emerging concerns as identified through CDC working groups and initiatives (e.g., CDC Strategic Priorities, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria priorities: https://www.hhs.gov/sites/default/files/PACCARB%20NAP%20Report%20FINAL%20Approved%20by%20Council.pdf)?

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?

- Does the project utilize critical partnerships or collaborations?
- Does the application highlight engagement with public health, healthcare epidemiology, and clinical partners?
- Do the investigators have access to sufficient computational resources to perform the planned studies?
- Is there sufficient engagement with individuals with demonstrated clinical expertise, including healthcare epidemiology, in the design and interpretation of research projects?
- Is there collaboration among investigators with specialized expertise, both within and among institutions, as corroborated by letters of support describing previous and existing collaborative projects?
- Is there sufficient engagement with persons with clinical expertise and healthcare epidemiology in the design of research aims to maximize the likelihood that model findings will be used to improve the practice of healthcare epidemiology and clinical practice?
- Do the investigators demonstrate a willingness to collaborate with other MInD-Healthcare investigators and share data generated through this award?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of

children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs

exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office.
Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Listed below are additional funding preferences, **in priority order**, that may be taken into consideration in the funding recommendation process:

- Funding recommendations may consider elimination of redundant lines of research in the program portfolio as a whole (e.g., preference may be given to unique model structures or model elements that would ensure a diversity of approaches across the research network when there are multiple models utilizing the same broad methodological approaches).
- Funding recommendations may also consider maximizing geographic diversity of dataset(s) proposed, both in the U.S. and overseas (greatest diversity will be achieved by the selection of awardees in both the U.S. and overseas, with applications focusing on transmission settings relevant to the U.S.) to maximize generalizability of the results. Geographic diversity will be defined in the US using the following regions: https://www2

.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred,

suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

CDC Administrative Requirements:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-20: Conference Support

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-23: Compliance with 45 C.F.R. Part 87

AR-25: Policy on Public Health Research and Non-research Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 – FY 2012 Enacted General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

AR-36: Certificates of Confidentiality

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http:// www.cdc.gov/ od/OGS /funding/ grants/additional_ req.shtm.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences

and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright

agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application and the summary of reviewers' comments for the application may be shared with the CDC staff who will provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC grant regulations and policies.
- **A Scientific Program Officer in the NCHHSTP Extramural Research Program Office (ERPO) will be responsible for the normal scientific and programmatic stewardship of the award as described below:**
    - Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award;
    - Serve as the primary point of contact on official award-related activities including an annual review of the grantee's performance as part of the request for

continuation application;
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
- Carry out continuous review of all activities to ensure objectives are being met;
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitor performance against approved project objectives.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access.
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- Ensuring that publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Conducting a five-year research program designed to use transmission modeling to better understand and defeat HAIs and related antimicrobial resistance.
- Ensuring that each budget year includes costs to support travel to Atlanta, Georgia, for two to four staff (i.e., the Principal Investigator, Co-Investigator(s) or Project Manager(s)) to attend planning and Steering Committee meetings with CDC staff and other awardees.
- Actively participating as a member of the MInD-Healthcare Network Steering

Committee. This includes attending annual grantee meetings in Atlanta convened by CDC staff and participating in regular communication with other members of the Steering Committee through regular teleconferences.
- Working collaboratively within the MInD-Healthcare Network Steering Committee to guide project development over the project period including the development of projects including at least two MInD-Healthcare sites to be described in the continuation application (i.e., collaborative projects). The Steering Committee will not serve as an advisory committee to the CDC.
- Communicating with the CDC Project/Scientific Program Officers about research progress, budgetary changes, and upcoming deadlines for ethical review.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards and will have responsibility for:

- Assisting the PI, as needed, in complying with the Extramural Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- After awards have been made, CDC staff will provide technical assistance regarding goals, data, and suitable methods, where appropriate.
- Participating in data analysis, interpretation of results, dissemination and publication of results, if CDC contribution so merits.
- Carrying out continuous review of all activities to ensure project objectives are being met.
- Attending committee meetings and participating in conference calls for the purposes of assessing overall progress and for program evaluation purposes.
- Assisting, as appropriate, the recipient in all stages of the program and providing programmatic and technical assistance to the recipient in all aspects of the science, including protocol development.
- Providing technical assistance to the MInD-Healthcare Network Steering Committee.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and

for OMB-PRA review, if needed.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent

upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?

- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan,

challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the period of performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to

answer questions from potential applicants.

Application Submission Contacts
Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contact

Amy Yang, Ph.D.

Extramural Research Program Office

Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS US8-1

Atlanta, GA 30333

Telephone: 404-718-8836

Email: AYang@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS US8-1

Atlanta, GA 30333

Telephone: 404-718-8833

Email: GAnderson@cdc.gov

Financial/Grants Management Contact

Dwayne Cooper

Office of Financial Resources/Office of Grant Services

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2939 Brandywine Road, MS TV-2

Atlanta, GA 30341

Telephone: 770-488-2874

Email: yih4@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Public Health Service Act, Sections 301(a) [42 USC 241(a)], 307 [42 USC 242*l*], and 317(k)(2) [42 USC 247b(k)(2)], as amended.