**SUMMARY STATEMENT**

**PROGRAM CONTACT:**
**EMERALD Nguyen**
**3015551212**
**emerald.nguyen@nih.gov**

**( Privileged Communication )**

***Release Date:*** **02/24/2023**
***Revised Date:***

***Application Number:*** **1 R21 AG083393-01**

**Principal Investigator**

**SANTOS-LOZADA, ALEXIS R**

**Applicant Organization: PENNSYLVANIA STATE UNIVERSITY, THE**

***Review Group:*** **SSPA**
**Social Sciences and Population Studies A Study Section**

***Meeting Date:*** **02/02/2023**
***Council:*** **MAY 2023**
***Requested Start:*** **07/01/2023**

***RFA/PA:*** **PA20-195**
***PCC:*** **2CMSFNG**

***Project Title:*** **The impact of Medicaid expansion on the rural mortality penalty in the United States**
***SRG Action:*** **Impact Score:41 Percentile:26 +**
***Next Steps:*** **Visit https://grants.nih.gov/grants/next_steps.htm**
**Human Subjects:** **X4-Human subjects involved - Exemption #4 designated**
**Animal Subjects:** **10-No live vertebrate animals involved for competing appl.**

| Project Year | Direct Costs Requested | Estimated Total Cost |
|---|---|---|
| 1 | 150,000 | 241,501 |
| 2 | 125,000 | 201,250 |
| TOTAL | 275,000 | 442,751 |

**ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.**

**1R21AG083393-01 Santos-Lozada, Alexis**

**RESUME AND SUMMARY OF DISCUSSION:** In this application, the investigators propose to estimate the contribution of state-level variation in Medicaid expansion to rural-urban mortality disparities among people aged 19-64, with attention to whether the rural-urban mortality differences changed during the COVID-19 pandemic. During discussion, the reviewers agreed that the proposed project addresses a highly significant and policy relevant topic because urban/rural differences have not been well explored yet in relation to Medicaid expansion. If successful, the findings may further understanding about the roots of disparities by demonstrating how variable Medicaid thresholds might affect rural-urban mortality differences. The well-qualified investigative team has experience with the methods and dataset to be used. Other key strengths include the novel attention to rural-urban differences, a focus on variation by subgroups, strong mortality data, and strategies to account for incremental changes in eligibility for Medicaid. However, reviewers raised several concerns about the approach. There is insufficient attention to the mechanisms through which Medicaid expansion may influence mortality; the application seems to assume the effects would operate solely through individual insurance eligibility without considering the effect of Medicaid expansion on whether or not rural hospitals stayed open. There is a lack of detail regarding the differences-in-differences models to be used and some concern about insufficient statistical power for some subgroup analyses. Other limitations include inadequate attention to potential selection bias in Medicaid coverage, insufficient consideration of treatment heterogeneity effects across units and over time, and an underdeveloped COVID-19 aim. Lastly, reviewers disagreed about whether people aged 65 and older should have been included. Some argued they should be in the study because one might expect the biggest mortality consequences for older people. In contrast, other panelists were comfortable that, although there may be spillover effects on older populations, it was reasonable to focus on the ages for which Medicaid expansion was directly applicable. Overall, the reviewers agreed that the application is potentially highly significant, but limitations in the approach reduce the overall impact on the field of mortality research to a moderate level.

**DESCRIPTION (provided by applicant):** Rural areas in the United States (U.S.) have exhibited higher mortality rates than urban areas since the late 1990s, a pattern known as the rural mortality penalty. Recent research has found that the rural mortality penalty continues growing due to mortality associated with preventable causes (metabolic and cardiovascular causes, alcohol use, and mental health). The expansion of Medicaid adopted by many states in the U.S. had the potential to reduce death due to these and other causes by facilitating access to healthcare to people who were not eligible under previous eligibility thresholds. While some state in the nation adopted this expansion, a process that started in 2014, others rejected it. While the adoption/rejection of this expansion is well-documented, little is known about the role the adoption of this policy at the state level impacted well-established demographic phenomenon such as the rural mortality penalty. This project requests access to restricted data to produce mortality rates for the population aged 19-64, by sex and by race/ethnicity to conduct a novel analysis of the differences observed in the rural mortality penalty employing a difference-in-difference design. The project evaluate whether the Medicaid expansion impacted the rural mortality penalty emphasizing the overall population, and disparities by sex and race/ethnicity. The project will also be the first to explore whether the COVID-19 pandemic impacted rural/urban mortality dynamics based on state-level adoption of the expansion of Medicaid by 2020. The analytic approach will combine formal and mathematical demographic methods with novel statistical models to evaluate the impact of the expansion of Medicaid in rural/urban mortality dynamics. Findings from this project will illustrate the role that state-level policies have in shaping diverging or congruent trajectories in mortality and in the face of the ongoing COVID-19 pandemic.

**PUBLIC HEALTH RELEVANCE:** The purpose of this project is to (1) estimate age-specific mortality rates for rural and urban areas by state, Medicaid expansion status, sex, and race/ethnicity (2) to study the effect of Medicaid expansion on rural mortality penalty using data from 1999 until 2019, and (3) to determine whether states that expanded Medicaid witnessed differential mortality increases during the first two years of the COVID-19 pandemic (2020 and 2021). This project will use restricted NCHS mortality data, census population estimates, rural-urban continuum codes, standardization techniques, and regression- based research design to examine the effect of Medicaid expansion on rural and urban age-specific mortality rates for the population aged 19-64, by sex, and by race/ethnicity. The project will also evaluate the disparities in mortality observed in the first two years of the COVID-19 pandemic at the intersection of residential context and state policies.

**CRITIQUE 1**

Significance: 2
Investigator(s): 2
Innovation: 4
Approach: 4
Environment: 2

**Overall Impact:** This proposal wishes to study the impact of Medicaid expansions on the rural/urban mortality disparities in the US. While mortality effects have been found, the differential impact on rural vs. urban areas has not yet been examined. They also propose to use not just the ACA-Medicaid expansions, but also use the income/asset test changes within a state to identify the relationship between Medicaid and urban/rural mortality differences. They will also examine whether Medicaid expansion mitigated the mortality rates during the height of the COVID pandemic (2020-2021). The project uses restricted mortality data, and applies difference-in-difference research methodologies. Overall, this is a strong proposal with a sound scientific premise and it employs rigorous methodologies. The team is strong with significant experience with these data and methods. I have a few concerns with the proposed analytic plan, especially with how to address the COVID pandemic, but these limitations could be overcome. Overall, I think this proposal has the potential for high impact.

**1. Significance:**

**Strengths**

- New margin for which to study the role of Medicaid on mortality.
- Nice use of the COVID pandemic to see if Medicaid has a differential protective effect.

**Weaknesses**

- Medicaid expansion will have a heterogenous effect across states, and even heterogenous effects on the urban/rural mortality rates, based on a variety of factors, which is largely ignored here.

**2. Investigator(s):**

**Strengths**

- Strong team, which experience using these data and methods.

**Weaknesses**

- None noted by reviewer.

**3. Innovation:**

**Strengths**

- Novel to examine Medicaid's impact on the urban/rural mortality rates.

**Weaknesses**

- None noted by reviewer.

**4. Approach:**

**Strengths**

- Using restricted mortality data.
- Examining by sex and race/ethnicity.
- Appropriate methods for the task at hand.

**Weaknesses**

- COVID-19 hit states and localities differentially, including things like employment which could contribute to differences in who is covered on Medicaid at any given time in any given state for Aim 2. There was no discussion of this potential selection bias in Medicaid coverage/eligibility.
- Heterogenous effects – either by state or by urban/rural within a state -- largely ignored. These could be measured using some of the new difference-in-difference methodologies.
- Vague on which difference-in-difference methodology they will employ, although they do highlight the staggered timing.

**5. Environment:**

**Strengths**

- Penn State has the resources to support this endeavor.
- Experience using and accessing the restricted data; gaining secret sworn status now.

**Weaknesses**

- None noted by reviewer.

**Protections for Human Subjects:**

Not Applicable (No Human Subjects)
Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 2**

Significance: 2
Investigator(s): 1
Innovation: 3
Approach: 4
Environment: 1

**Overall Impact:** This new R21 application asks whether Medicaid expansion impacted rural-urban disparities in mortality in the U.S., with attention to what has been described as the “rural mortality penalty.” The work will focus on: 1) age-specific mortality rates for rural and urban areas by state and degree of Medicaid expansion for the population aged 19-64, by sex and race/ethnicity (1999-2021); 2) if/how states that expanded Medicaid observed changes in their age-adjusted mortality rates, and on their rural mortality penalty (1999-2019); and 3) if/how the rural mortality penalty changed during the COVID-19 period (2020-2021) based on Medicaid expansion by 2020. The research described is highly significant, with a focus on the rural mortality penalty and potential differences by sex and race/ethnicity. Access to care is one potential determinant of the urban-rural disparity observed; the data compiled and the analyses proposed could bring insights into whether, and to what degree, such programmatic efforts mattered for mortality differentials. This promising application might benefit from a focus on the first two specific aims. The COVID piece, although important, feels a bit like an add-on; the inclusion is not well-justified, and the span of assessment truncated. Additional concerns rest with the lack of conceptual framework to guide the analyses, and an acknowledgement that “rural” location is much harder to ascertain than urban (and may require more than one data source to distinguish and validate). Acknowledging those caveats, the work described could enhance our understanding of mortality differentials by location.

**1. Significance:**

**Strengths**

- Rural-urban disparities in mortality are critical to explore, particularly in the context of a significant policy effort to expand access to care.
- The ability to examine differences by race/ethnicity and sex in the context of Medicaid expansion is important.
- The proposal is well-structured, and extensions of the research easily imagined.
- The rigor of prior research is described, and the extent to which this work will build on previous efforts.

**Weaknesses**

- None noted by reviewer.

**2. Investigator(s):**

**Strengths**

- Dr. Santos-Lozada is well-positioned to lead this R21; he has the requisite skills and expertise to carry out the project as described.
- Dr. Rhubart contributes additional knowledge on rural-urban disparities and Medicaid expansion processes and timing.
- Dr. Fisher brings specific statistical expertise to the research team.

**Weaknesses**

- None noted by reviewer.

**3. Innovation:**

**Strengths**

- A focus on the rural mortality penalty, and how it has been altered by state-level Medicaid expansion, is novel.
- The variation related to the rollout is a nice analysis feature to exploit, and contributes to the unique contribution of the work.

**Weaknesses**

- Some form of conceptual framework would help to guide the work and, later, the interpretation of results. What, for instance, distinguishes health services or health-seeking behavior in these two contexts? How might Medicaid expansion play out differently? How might that matter for the timing of mortality for, say, some exemplar conditions?
- The COVID component is not well-integrated into the larger research effort.
- The difference-in-difference approach is this context is useful, but the method itself not particularly innovative.

**4. Approach:**

**Strengths**

- Attention to variation in income eligibility thresholds for Medicaid is an important feature of the analysis plan, as is attention to variation in timing of the rollout.
- The difference-in-difference approach is appropriate for the analysis of Medicaid expansion.
- The detailed description of the approach suggests a robust and unbiased approach, and one that builds on prior research.
- Relevant biological variables, such as sex, are addressed in the application and included in the analysis plan.

**Weaknesses**

- What is the rationale for using RUCC codes versus, say, RUCA codes or other codes to classify the urban-rural continuum? Some justification, along with potential limitations of the metric selected, would be useful. Perhaps introduce an additional metric for validation?
- Rurality has been shown to be muddier to classify that urbanicity (see Bennett et al., 2019 in *Health Affairs*; Long, Delamater and Holmes, 2021 in *Medical Care*). Some discussion of what “rural” is meant to capture would benefit the work and potentially speak to the issue of coding choice above. Relatedly, why dichotomize when more detailed information is available?

- The county reclassification issue may be more challenging in some states than others, and may require closer attention to change than merely comparisons by decade on either end of 2003.
- On Aim 3, why only the first two years of the COVID pandemic period? Also, how will state-level variation in both policy approaches and COVID rates be incorporated into the analyses?

**5. Environment:**

**Strengths**

- The Pennsylvania State University provides an excellent and supportive environment for the proposed research.

**Weaknesses**

- None noted by reviewer.

**Protections for Human Subjects:**

Not Applicable (No Human Subjects)
Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Applications from Foreign Organizations:**

Not Applicable (No Foreign Organizations)

**Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Not Applicable (No Relevant Resources)

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 3**

Significance: 2

Investigator(s): 1
Innovation: 5
Approach: 7
Environment: 1

**Overall Impact:** This proposal seeks to estimate the contribution of state-level variation in the Medicaid eligibility threshold to the rural mortality penalty. That this state-level policy decision may contribute to the national-level rural penalty is plausible based on prior literature, and identifying the sources of rural mortality has important policy implications. However, the proposal does not justify some core pieces of analytical logic in the operationalization of the treatment and framing of the question. These weaknesses marred enthusiasm for what would otherwise be a useful and relevant study.

**1. Significance:**

**Strengths**

- Rising rural mortality is a problem of substantial public health importance. Rural working-age adults disproportionately live in states with delayed or absent Medicaid expansion under the Affordable Care Act, making reduced Medicaid eligibility (relative to other states) a *prima facie* plausible contributing factor to worsening rural mortality even as urban mortality continued to improve in many places.

**Weaknesses**

- The proposal does not present a compelling reason to limit the study population to those aged 19-64. Even if individuals aged 65+ have Medicare, they may be dual-eligible depending on Medicaid eligibility, and regardless of insurance, their medical care may be substantially affected by local hospital context that (especially in rural areas) can be substantially affected by whether or not the state expanded Medicaid eligibility. Therefore, it is not clear why they are excluded from the study. More broadly, the proposal seems to assume, without spelling this out, that the only pathway through which Medicaid matters to health is via individual insurance coverage rather than effects on the local health system.
- The proposal does not spell out why it is important to understand the rural-urban mortality differential in particular (vs., say, the level of rural mortality).
- The proposal does not spell out why we would expect Medicaid coverage thresholds to affect mortality differentials specific to the Covid-19 pandemic (while Covid treatments were free regardless of insurance), what we might expect to find, or how we should interpret any relationships uncovered.

**2. Investigator(s):**

**Strengths**

- The team has all the necessary expertise to carry out the study. The PI, while early in their career, is accomplished in demographic health modeling.

**Weaknesses**

- None identified.

**3. Innovation:**

**Strengths**

- Gradated measures of both Medicaid coverage (based on variable eligibility thresholds, many of which changed under the Affordable Care Act but to varying degrees) and rural/urban status allow a nuanced look at this relationship.

**Weaknesses**

- The proposal does not engage with recent critiques of differences-in-differences approaches or innovations in their application (such as Goodman-Bacon decomposition, Sun and Abraham's IW estimator, etc.). These seem particularly relevant given that I would expect a lot of treatment heterogeneity (across units and over time) depending on whether local hospitals continued to operate or closed as a function of lack of Medicaid expansion.

**4. Approach:**

**Strengths**

- Age-standardization adjusts for differences in age composition.
- Attention to county reclassification problem.
- Theoretically-justified attention to potential sex-specific results.

**Weaknesses**

- In analyses using a continuous treatment variable or continuous rural/urban measure, no functional form is specified. In the case of the rural/urban spectrum, it is not clear whether we should expect the effects of Medicaid expansion to be monotonically increasing or monotonically decreasing across this spectrum.
- It seems implausible that it will be possible to identify effects, with statistical confidence, for such small populations as (for example) rural Asian or Pacific Islander populations. The power analysis presented indicates that 246 observations are needed to detect reasonably-sized effects, but this seems to be based only on the dichotomous rural/urban distinction, rather than the 9-category rural/urban continuum discussed elsewhere. In addition, the assessment of what constitutes a reasonably-sized effect is based on rural/urban differences in crude mortality, which are inflated by age distribution differences.
- The statement that age-specific mortality rates are not publicly available past 2016 is puzzling.

**5. Environment:**

**Strengths**

- The environment offers all resources necessary to carry out this study, including, notably, RDC access.

**Weaknesses**

- None identified.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

- Determined to be exempt from review; assurance number provided

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

**Inclusion Plans:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion Based on Age: Distribution not justified scientifically
- As explained in comments above, the scientific rationale for excluding those aged 65+ is not clear.

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Applications from Foreign Organizations:**

Not Applicable (No Foreign Organizations)

**Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Acceptable

- It would be helpful to identify which data will be made public (since the underlying data are restricted) and where they will be posted (i.e., in a permanent repository).

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

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Footnotes for 1 R21 AG083393-01; PI Name: Santos-Lozada, Alexis R

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

**MEETING ROSTER**

**Social Sciences and Population Studies A Study Section**
**Population Sciences and Epidemiology Integrated Review Group**
**CENTER FOR SCIENTIFIC REVIEW**
**SSPA**
**02/02/2023 - 02/03/2023**

**Notice of NIH Policy to All Applicants:** Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-22-044 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html, including removal of the application from immediate review.

**CHAIRPERSON(S)**

CAGNEY, KATHLEEN A, PHD
DIRECTOR
INSTITUTE FOR SOCIAL RESEARCH
UNIVERSITY OF MICHIGAN
ANN ARBOR, MI 48106

**MEMBERS**

ANGLEWICZ, PHILIP A, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF POPULATION, FAMILY
AND REPRODUCTIVE HEALTH
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21205

CASEY, JOAN A, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF WASHINGTON
SEATTLE, WA 98105

COE, NORMA B, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICAL ETHICS AND HEALTH POLICY
PERELMAN SCHOOL OF MEDICINE
UNIVERSITY OF PENNSYLVANIA
PHILADELPHIA, PA 19105

CRUMP, CASEY, MD, PHD
PROFESSOR AND VICE CHAIR FOR RESEARCH
DEPARTMENT OF POPULATION HEALTH SCIENCE AND POLICY
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
NEW YORK, NY 10029

DILLEY, JULIA A, PHD
SENIOR RESEARCH SCIENTIST/EPIDEMIOLOGIST
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION
AND MULTNOMAH COUNTY HEALTH DEPARTMENT
PROGRAM DESIGN AND EVALUATION SERVICES
PORTLAND, OR 97232

GALAMA, TITUS J, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF ECONOMICS
DORNSIFE CENTER FOR ECONOMIC AND SOCIAL RESEARCH
UNIVERSITY OF SOUTHERN CALIFORNIA
LOS ANGELES, CA 90089

GEE, GILBERT, PHD
PROFESSOR AND CHAIR
DEPARTMENT OF COMMUNITY HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF CALIFORNIA, LOS ANGELES
LOS ANGELES, CA 90095

GLYMOUR, MEDELLENA M, SCD
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA 94158

GREEN, TIFFANY, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF POPULATION HEALTH SCIENCES
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY
UNIVERSITY OF WISCONSIN
MADISON, WI 53593

HANDA, SUDHANSHU, PHD
INSTITUTE FELLOW - AMERICAN INSTITUTES FOR RESEARCH
KENAN EMINENT PROFESSOR
DEPARTMENT OF PUBLIC POLICY
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
CHAPEL HILL, NC 27599

HUDSON, DARRELL LEE, PHD
ASSOCIATE PROFESSOR
BROWN SCHOOL OF SOCIAL WORK
WASHINGTON UNIVERSITY
ST LOUIS, MO 63130

JUTLA, ANTARPREET, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF ENVIRONMENTAL ENGINEERING SCIENCES
UNIVERSITY OF FLORIDA
GAINESVILLE, FL 32611

KERSHAW, KIARRI N, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF PREVENTIVE MEDICINE
FEINBERG SCHOOL OF MEDICINE
NORTHWESTERN UNIVERSITY
CHICAGO, IL 60611

LIVINGSTON, MELVIN D, PHD
RESEARCH ASSOCIATE PROFESSOR
DEPARTMENT OF BEHAVIORAL SCIENCES AND HEALTH EDUCATION
ROLLINS SCHOOL OF PUBLIC HEALTH
EMORY UNIVERSITY
ATLANTA, GA 30322

MADHAVAN, SANGEETHA, PHD
PROFESSOR AND CHAIR
DEPARTMENT OF AFRICAN-AMERICAN STUDIES & SOCIOLOGY
UNIVERSITY OF MARYLAND
COLLEGE PARK, MD 20742

MAGNUSON, KATHERINE, PHD
PROFESSOR
DIRECTOR OF THE INSTITUTE FOR RESEARCH ON POVERTY
SCHOOL OF SOCIAL WORK
UNIVERSITY OF WISCONSIN-MADISON
MADISON, WI 53706

MONTEZ, JENNIFER KARAS, PHD
UNIVERSITY PROFESSOR
DEPARTMENT OF SOCIOLOGY
SYRACUSE UNIVERSITY
SYRACUSE, NY 13244

PERRY, BREA L, PHD
PROFESSOR
DEPARTMENT OF SOCIOLOGY
INDIANA UNIVERSITY
BLOOMINGTON, IN 47405

SANCHEZ, BRISA N, PHD
DORNSIFE ENDOWED PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS
DORNSIFE SCHOOL OF PUBLIC HEALTH
DREXEL UNIVERSITY
PHILADELPHIA, PA 19094

SCHEPIS, TY S, PHD
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
TEXAS STATE UNIVERSITY
SAN MARCOS, TX 78666

SICONOLFI, DANIEL, PHD *
BEHAVIORAL SCIENTIST
RAND CORPORATION
PITTSBURGH, PA 15213

VERDERY, ASHTON MICHAEL, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF SOCIOLOGY AND CRIMINOLOGY
PENNSYLVANIA STATE UNIVERSITY
UNIVERSITY PARK, PA 16801

VILLALONGA OLIVES, ESTER, PHD *
ASSISTANT PROFESSOR
SCHOOL OF PHARMACY
UNIVERSITY OF MARYLAND
BALTIMORE, MD 21201

WRIGLEY-FIELD, ELIZABETH, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF SOCIOLOGY
UNIVERSITY OF MINNESOTA
MINNEAPOLIS, MN 55455

## MAIL REVIEWER(S)

SWARUP, SAMARTH, PHD
RESEARCH ASSOCIATE PROFESSOR
BIOCOMPLEXITY INSTITUTE & INITIATIVE
UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE, VA 22904

## SCIENTIFIC REVIEW OFFICER

RYAN, SUZANNE, PHD
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

## EXTRAMURAL SUPPORT ASSISTANT

SMITH, ALETHIA ALEXANDREA
EXTRAMURAL SUPPORT ASSISTANT
THE CENTER FOR SCIENTIFIC REVIEW
THE NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

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