

A Longitudinal Examination of Mental and Physical Health among Police Associated with COVID-19

Supporting Statement Section A

New

**Request for Office of Management and Budget (OMB) Review and Approval for a Federally
Sponsored Data Collection**

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Section A

1.

- **Goals of the study:** The overarching goal of this study is to evaluate the longitudinal consequences of the COVID-19 pandemic on the mental and physical health of police officers.
- **Intended use of the resulting data:** Given the high rates of mental and physical health issues in the policing population this study could lead to new knowledge about police specific occupational stressors during a pandemic and identify risk and protective factors that may be used to mitigate these stressors.
- **Methods to be used to collect:** Longitudinal study
- **The subpopulation to be studied:** Police officers
- **How data will be analyzed:** Descriptive analyses for demographic and lifestyle variables; regression models, analysis of covariance, longitudinal modeling will be used evaluate the relationship between biological and psychological markers of disease over time.

Circumstances Making the Collection of Information Necessary

This is a new information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The request is for two years to complete data collection. This data collection is authorized by Section 20(a)(1) of the Occupational Safety and Health Act (29 U.S.C. 669) (Appendix A).

The mission of NIOSH is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act of 1970, Public Law 9-596 (Section 20) [a][1] authorizes NIOSH to conduct research to advance the health and safety of workers. Similarly, the Centers for Disease Control and Prevention's Health Protection Goals include a Healthy Workplace goal to "promote and protect the health and safety of people who work by preventing workplace-related fatalities, illnesses, injuries, and personal health risks." The proposed project will provide needed information for addressing these goals in police officers, an essential worker population. The results of this data collection can elucidate the biological and psychological risk factors associated with COVID-19 as well as the necessary knowledge needed to develop specific interventions to address stress and illness among police officers.

The corona virus disease 2019 (COVID-19) is a significant health hazard. To date over 81 million individuals worldwide have been diagnosed with COVID-19, and over 1.7 million have died [1]. COVID-19 has resulted in significant increases in depression, anxiety, distress, and insomnia [2]. The economic consequences are also unprecedented, with the US economy expected to shrink by \$8 trillion dollars over the next ten years [3]. Similarly, COVID has had repercussions in the police [4-6]. How persons in authority address such disasters is a matter of concern because it not only affects the people they serve, but also themselves. Police officers need to remain healthy and ready to perform at their peak during such crises. Preliminary research shows that COVID contributes to increased physical and psychological stress load. For police officers, this quickly changing landscape can result in very high

levels of stress, which can overload an individuals' adaptive response, challenge their understanding of the world and result in mental and physical health issues [7-11]. This may be particularly true of police officers who have been charged with protecting the public, maintaining civil order, and dealing with their own personal losses. Given that efficiently performing officers are key to successful functioning of law enforcement, addressing police mental and physical health is imperative for their wellbeing as well as that of the public they serve. Nonetheless, little research has been conducted to evaluate the physical and mental health consequences of the COVID-19 pandemic on police officers. Therefore, this research effort is designed to evaluate the longitudinal mental and physical health effects of COVID-19 on approximately 200 police officers.

Previously, in collaboration with NIOSH, the University of Buffalo at New York (UB) conducted a cross-sectional research project entitled the "Buffalo Cardio-Metabolic Occupational Police Stress "(BCOPS) study. The aim of the project was to evaluate the psychological, physiological, and subclinical measures of mental and physical health in Buffalo, NY police officers. The BCOPS study itself includes a baseline examination and four follow-up examinations. For this reason, NIOSH has extensive mental and physiological health data on police officer obtained *prior to* COVID-19, including stress related surveys, blood parameters, physical measures, stress biomarkers (cortisol) and telomere length data. To meet the aims of this study NIOSH has contracted with UB. A subset of the surveys used in the BCOPS studies will be repeated for this survey. By comparing the responses of the surveys prior to COVID-19 to those obtained during this study, NIOSH can evaluate the longitudinal biological and psychological health effects of COVID-19 on the police officers.

The project specific aims are:

Specific Aim 1: To evaluate the impact of COVID-19 on police officers including the longitudinal psychological and biological measures of stress pre-pandemic to those collected during COVID-19 and psychological measures of stress 6-8 months later.

Hypothesis 1: Measures associated with COVID-19 are associated with worsening psychological (e.g. depression, anxiety, PTSD) changes over time.

Hypothesis 2: Measures associated with COVID-19 are associated with worsening biologic changes (e.g. higher salivary cortisol, metabolic syndrome, inflammatory markers) over time.

Hypothesis 3: Measures associated with COVID-19 will be associated with worsening mental health observed at the follow-up exam.

Specific Aim 2: To examine resiliency, hardiness, and coping as it modifies/mediates mental and physical stress.

Hypothesis 1: Resiliency, hardiness, and active coping modify/mediate the associations observed in specific aim 1, hypothesis 1 and 2.

Specific Aim 3: To longitudinally examine the impact of stress on cellular aging (telomere length) and stress associated with the COVID-19 pandemic.

Hypothesis 1: Measures of COVID-19 will be associated with shorter telomere length.

Specific Aim 4: Translate and communicate study findings in peer reviewed, stakeholder, and various media outlets.

Given the high rates of mental and physical health issues in the policing population this study could lead to new knowledge about police specific occupational stressors during a pandemic and identify risk and protective factors that may be used to mitigate these stressors.

2. Purpose and Use of Information Collection

The purpose of the proposed research is to longitudinally measure changes in psychological stress and physical health markers of police officers during COVID-19 and mental health measures after the COVID-19 pandemic as well as police experiences during COVID-19. Therefore, NIOSH has contracted services to support the completion of this study, specifically to evaluate the impact of COVID-19 on police officers including the longitudinal mental and physical health effects of the COVID-19 pandemic on police officers. To meet NIOSH's need, UB will collect mental and physical health data on approximately 200 police officers.

This data will consist of markers of disease such as blood pressure, measurement of lipids, glucose, and insulin, measurement of body fat and salivary cortisol. Psychosocial factors detrimental to health such as perceived stress, work stress, depression, as well as protective factors (e.g. resiliency and coping) will also be examined. A complete list of the measurements that will be taken as part of this study can be found in Table 1 (Appendix C). The list of surveys that will be completed by the participants are in Appendix D.

To meet the aims of this study there will be two rounds of data collections. The first round will consist of collecting both the mental and physical health data. The second round, one year later, will consist of collecting mental health data only. All data will be cleaned and entered into a database at UB. It will then be delinked-deidentified prior to being sent to NIOSH for analyses. Data collected as part of this survey will be compared to the same mental and physical health data that was collected *prior* to COVID-19 as part of the BCOPS study. All participants will sign a consent form prior to their participation in the study (Appendix E).

This data collection is necessary for several reasons. First, it will be one of the first studies to evaluate the mental and physical health effects in police officers during a pandemic. Secondly, because NIOSH has data on this cohort of police officers collected prior to COVID-19, NIOSH is in a rare position to assess the longitudinal associations between occupational stressors, COVID-19, and their effects on the mental and physical health of police officers. A third factor is the wide variety of data that NIOSH will be collecting. Variables include subclinical cardiovascular disease markers, psychological stress, and measures of work history and sleep. The knowledge gained from this study will provide the foundation for future intervention studies designed to reduce the psychological and biological health consequences of another pandemic in law enforcement officers and potentially other emergency responders. This can lead to improvements in their well-being with a potential for a reduction in the burden of disease among officers whose jobs are essential to society.

If the questionnaires are not administered, NIOSH cannot meet the aims of this study. There is no data on the mental and physical health effects of COVID-19 on police officers, therefore there is no other data that can be used in lieu of this data collection. Therefore, police and public health officials would lack the necessary knowledge about potential measures that may be taken to mitigate the effects of a pandemic in police officer, which could have direct consequences on the officers and the public they serve.

This data collection has been peer-reviewed, approved, and fully funded.

3. Use of Improved Information Technology and Burden Reduction

No automated, electron, mechanical, or other technological collection techniques will be used for this data collection. Paper questionnaires will be used in this collection and keyed into a database management system.

This study will only collect data necessary to meet the aims of this study and will only include questions that provide information not available from other sources. This will consist of psychological and biological health measures. It will also include basic demographic and medical history information (see Table 1, Appendix C).

4. Efforts to Identify Duplication and Use of Similar Information

Based on historical knowledge, research conducted on private industry, and university research there are no other studies that are comparable to the unique characteristics of this data collection. There are no other studies that have extensively collected psychological and biological data across multiple time points that can meet the aims of this study. There are also no other studies currently evaluating the longitudinal mental and physical effects of COVID-19 in police officers.

5. Impact on Small Businesses or Other Small Entities

This collection will not impact small businesses. This participants for this study are police officers.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection at two time points. If this data collection does not take place, NIOSH will be unable to understand the psychological and biological impact of COVID-19 on police officers that could lead to new knowledge about police specific occupational stressors during a pandemic and identify risk and protective factors that may be used to mitigate these stressors.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on 01/26/2021, Vol. 86, No. 15, pages 7095-7096. One non-substantive comment was received.

B. This project was reviewed and approved through the CDC IMS 2019 NCOV Response Worker Safety Health Task Force.

9. Explanation of Any Payment or Gift to Respondents

Participants will receive a token of appreciation for participating in this study.

The American police population is noted for resistance to provision of information [12, 13]. The police have been described as a highly cohesive closed society that often refuses those outside of the organization access to either information or personnel. Police officers are hesitant to divulge

information to investigators for fear that it may compromise their position or safety. Sharing health and confidential information is a concern in all occupational cohorts, but particularly the police and represents a real obstacle to successful recruitment.

A token of appreciation is being given to the police officers for three reasons. First, based on the uniqueness of this population and the fifteen years of research experience UB has had with the Buffalo police while conducting the BCOPS studies, a token of appreciation is seen as essential for participation. Without the token of appreciation, UB asserts that they will not be able to reach the participation goal of 200 police officers. Secondly, given the amount of time the person is participating, approximately 3 hours and collecting saliva outside of clinic over the course of a day a \$150 incentive is seen as reasonable. The second round of surveys will take approximately one hour with a token of appreciation of \$50. Lastly, these officers have participated in BCOPS studies over the last fifteen years and have received a token of appreciation when they participate in studies conducted by UB. Although historical precedent should not dictate the token of appreciation, with this population, at this time, it is anticipated that the lack of a token of appreciation might actually serve as a disincentive to participation.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NIOSH Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. The questionnaire responses will not be retrieved using personal identifiers. In addition, no personally identifying information (PII) will be recorded (e.g. names, social security numbers, or any other unique identifier) as a part of the dataset. All officers will be asked to sign a consent form prior to participation (Appendix C).

To meet the aims of this study, the officers who will be invited to participate in this study are limited to officers who previously participated in a BCOPS study. For this reason, the contractor will use previously obtain names and contact information (e.g. names, addresses) to contact those officers for the current study.

All the data received by NIOSH from the contractor will be stripped of personal identifiers, including names, social security numbers, addresses, or other data that directly identifies subjects. NIOSH will be unable to identify any individual participant and NIOSH staff will make no attempt to identify subjects. Only secure forms of electronic communication will be used to transfer information on study subjects between UB and NIOSH. The confidentiality of the information will be protected by the Privacy Act. All hard copy data will be stored in a secure locked location, with limited access by research personnel. Electronic data will be maintained on password protected computer files on site that will be accessible only to study personnel.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

For this study NIOSH will receive data collected by the contractor under UB IRB approval (Appendix F1). NIOSH will not have any interaction with study participants and will only receive deidentified-delinked data from the contractor therefore, while the population is human subjects this is non-exempt human subjects research as we will not be engaged with the participants (Appendix F1). NIOSH will rely on the non-CDC IRB approval (Appendix F2).

The questionnaires that will be administered as part of this study contain several questions that may be considered sensitive in nature, including questions regarding personal information, physical, and mental health information. Biological samples will also be collected for salivary cortisol measurement and telomere length analysis.

The list of questionnaires the participants will be asked to complete can be found in Table 1 (Appendix D). In order to meet the aims of this study, which is to evaluate the longitudinal mental and physical health effects of COVID-19 NIOSH will need to collect the same mental and physical health data that was previously collected as part of the BCOPS study.

Personal history questions include race/ethnicity questions and questions about alcohol and smoking will be asked as part of the demographic questions.

The medical history questionnaire also contains several potentially sensitive questions, because it specifically requests information about health conditions such as heart disease, diabetes, autoimmune conditions, and cancer.

Psychosocial factors detrimental to health such as work stress, depression, posttraumatic stress disorder, burnout as well as protective factors (e.g., resiliency and coping) will be examined.

The sensitive questionnaires are necessary to determine key mental and physical health issues associated with COVID-19. It is necessary for NIOSH to collect this data so that we can better understand the risk and protective factors associated with COVID-19 in order to make recommendations that might be able to mitigate stressors in police officers that lead to negative psychological and biological health outcomes, particularly related to COVID-19. The knowledge gained can guide future research on specific risks in police officers and how best to mitigate stressors like COVID-19.

The survey does not ask for respondent's social security number, sexual behavior, or religious attitudes.

All questionnaire response data will be treated in a secure manner and will not be disclosed, unless compelled by law. Aggregation of responses will ensure participants will not be identifiable.

12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs will accrue to the respondents other than their time to complete the questionnaires (round 1 and 2) and collection of biological samples (round 1 only).

The burden table lists the estimated population size of 200 police officers who will respond to 16 surveys, serological (blood) collection, and salivary cortisol at the first round. All officers who participate in the first round will be mailed the medical history questionnaire and psychosocial questionnaires 6-8 months later (second round). Biological samples will not be collected during the second round. It is possible that 10% of the participants will not present for testing during either the first or second round of data collection. Therefore, the total burden hours for 180 officers was estimated to be 596.

Table A12.1. Estimated Annualized Burden Hours

| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---------------------|---|-----------------------|------------------------------------|--|-------------------------|
| Police officers | Letter of Invitation | 240 | 1 | 1/60 | 4 |
| | Letter of Introduction | 200 | 1 | 7/60 | 28 |
| | Eligibility Screening Form | 200 | 1 | 5/60 | 17 |
| | Personal history | 180 | 1 | 2/60 | 6 |
| | Medical history | 180 | 2 | 8/60 | 48 |
| | Spielberger Stress Survey | 180 | 2 | 7/60 | 42 |
| | Center for Epidemiologic Studies Depression Scale | 180 | 2 | 2/60 | 12 |
| | Brief Copc | 180 | 2 | 3/60 | 18 |
| | Organizational Support Scale | 180 | 2 | 2/60 | 12 |
| | Maslach Burnout | 180 | 2 | 2/60 | 12 |
| | Fatigue Scale | 180 | 2 | 2/60 | 12 |
| | Posttraumatic Stress Disorder -5 | 180 | 2 | 2/60 | 12 |
| | Connor-Davidson Resiliency Scale | 180 | 2 | 1/60 | 6 |
| | Beck Anxiety | 180 | 2 | 3/60 | 18 |
| | Pittsburgh Sleep Quality Index | | 2 | 2/60 | 12 |
| | Beck Depression | 180 | 2 | 3/60 | 18 |
| | Beck Hopelessness | 180 | 2 | 2/60 | 14 |
| | COVID-19 (Round 1) | 180 | 1 | 3/60 | 9 |
| | COVID-19 (Round 2) | 180 | 1 | 3/60 | 9 |
| | Civil Unrest/Public | 180 | 2 | 3/60 | 17 |

| | | | | | |
|-------|-------------------------------|-----|---|-------|-----|
| | Perception/work environment | | | | |
| | Serological Sample collection | 180 | 1 | 1 | 180 |
| | Salivary Cortisol collection | 180 | 1 | 30/60 | 90 |
| Total | | | | | 0 |

B. The annualized cost to respondents for the burden hours for the collection of information

The estimated total cost to the respondent population for the questionnaire is \$17513.47 based on the average costs per burden hour and the burden hours as shown below. This burden will occur over two years of information collection.

Table A.12.2 Estimated Annualized Cost Burden to Respondents

| Type of Respondents | Form Name | Total Burden (in hours) | Hourly Wage Rate* | Total Respondent Costs |
|---------------------|---|-------------------------|-------------------|----------------------------|
| Police officers | Letter of Invitation | 1 | \$31.33 | \$31.33 |
| | Letter of Introduction | 7 | \$31.33 | \$219.31 |
| | Eligibility Screening Form | 5 | \$31.33 | \$156.65 |
| | Personal history | 6 | \$31.33 | ** Expression is faulty ** |
| | Medical history | 48 | \$31.33 | ** Expression is faulty ** |
| | Spielberger Stress Survey | 42 | \$31.33 | ** Expression is faulty ** |
| | Center for Epidemiologic Studies Depression Scale | 12 | \$31.33 | ** Expression is faulty ** |
| | Brief Cope | 18 | \$31.33 | ** Expression is faulty ** |
| | Organizational Support Scale | 12 | \$31.33 | ** Expression is faulty ** |
| | Maslach Burnout | 12 | \$31.33 | ** Expression is |

| | | | | |
|-------|---|-----|---------|----------------------------|
| | | | | |
| | Fatigue Scale | 12 | \$31.33 | ** Expression is faulty ** |
| | Posttraumatic Stress Disorder -5 | 12 | \$31.33 | ** Expression is faulty ** |
| | Connor-Davidson Resiliency Scale | 6 | \$31.33 | ** Expression is faulty ** |
| | Beck Anxiety | 18 | \$31.33 | ** Expression is faulty ** |
| | Pittsburgh Sleep Quality Index | 12 | \$31.33 | ** Expression is faulty ** |
| | Beck Depression | 18 | \$31.33 | ** Expression is faulty ** |
| | Beck Hopelessness | 14 | \$31.33 | ** Expression is faulty ** |
| | COVID-19 (Round 1 and Round 2) | 18 | \$31.33 | ** Expression is faulty ** |
| | Civil Unrest/Public Perception/work environment | 17 | \$31.33 | ** Expression is faulty ** |
| | Serological Sample collection | 180 | \$31.33 | ** Expression is faulty ** |
| | Salivary Cortisol collection | 90 | \$31.33 | ** Expression is faulty ** |
| Total | 0 | | | 0 |

*Hourly wage estimates were obtained from the U.S. Bureau of Labor Statistics on December, 2020 [14]. The estimated annual salary for a Buffalo, Ny police officer is approximately \$31.33 per hour.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional cost burdens to respondents or record keepers.

14. Annualized Cost to the Federal Government

The annualized cost to the government is \$796,355 the first year and \$619,64 for the second year. The total cost for the entire two years is \$1,416,000. Costs include personnel charges for NIOSH personnel, contractor cost, supplies, printing costs, and travel-related costs.

Table A14.1 Estimated Annualized Cost to the Federal Government

| | Year One | Year Two | Total Project Costs |
|--|----------|----------|---------------------|
|--|----------|----------|---------------------|

| | | | |
|-------------------|-----------|-----------|-----|
| NIOSH Personnel | \$66,412 | \$69,732 | \$0 |
| UB Contract | \$716,205 | \$549,413 | \$0 |
| Telomere Analysis | \$13,238 | \$0 | \$0 |
| Travel | \$500 | \$500 | \$0 |
| Total | \$0 | \$0 | \$0 |

15. Explanation for Program Changes or Adjustments

This is a new data collection

16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16.1 Project Time Schedule

| Activity | Year 1 | | | | Year 2 | | | |
|--------------------------------------|--------|---|---|---|--------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Staff training | X | | | | | | | |
| Recruitment under OMB waiver | X | X | X | X | X | | | |
| Examinations under OMB waiver | | X | X | X | X | | | |
| OMB Waiver Ends/OMB approval | | | X | X | X | X | X | X |
| Data entry & documentation | | | X | X | X | X | | |
| Data cleaning | | | X | X | X | X | | |
| Mental Health Survey- mail out | | | | X | X | X | X | |
| Clean and enter mental health survey | | | | | X | X | X | X |
| Data analysis | | | | | | X | X | X |
| Manuscript development | | | | | | | X | X |
| Presentations/workshops/seminars | | | | | | | X | X |

Because this is COVID-19 research, it was paramount that NIOSH start this study as soon as possible, therefore we obtained an OMB waiver and data collection began as soon as the contract was in place. However, because this is a two-year project NIOSH is submitting this OMB package to continue collecting data after the waiver expires. Due to the time sensitive nature of this project there can be no gap between the time that the data collection was begun and OMB approval for continued data

collection is granted. Therefore, NIOSH is submitting the OMB approval prior to the end of the OMB waiver expiring to bridge that gap and try to prevent any time delay between data collection.

Letters will be sent to officers asking them to voluntarily participate in this study (Appendix G). Recruitment will focus on recruiting 200 of the 240 officers who participated in the last BCOPS study then extended to any officer who participated in BCOPS until 200 officers have agreed, or there are no more officers to recruit. A letter of introduction will be sent to all officers who have agreed to participate (Appendix H). If an officer hasn't responded after two letters have been sent, UB will also contact them by phone. If the officer declines to participate they will no longer be contacted. For all officers who agree to participate, UB will coordinate the scheduling of officers with the police department and will not schedule officers more than one month in advance. Scheduling will be flexible.

At their designated appointment time, all participants will complete the paper and pencil questionnaires then complete the clinical exam, which will entail a fasting blood draw (approximately 4 tablespoons), measuring the participants' height, weight, abdominal height, waist circumference and neck circumference, and taking their blood pressure.

Cortisol saliva testing will be done outside of the clinic at the participant's residence by the participant. Participants will be provided with Salivettes (Sarstedt, USA), a commercially available collection device consisting of dental rolls and centrifuge tubes, to take with them when they leave the clinic for the collection of saliva samples. Participants will be given instructions on how to collect the samples to be taken the day after they leave the clinic- four samples in the morning when they awaken, one at lunchtime, one at dinner, and one when they go to sleep. The participant will be asked to return the saliva samples to the clinic when completed either in person or via paid postage. This ends the clinic visit. UB will advise the participant upon departing during round one that they would like to contact them again in about 6-8 months to complete the same surveys they did in the clinic.

Round Two

UB will conduct a follow-up survey approximately 6-8 months after the clinic visit. Each officer who participated in the first round and who agreed to participate in second round, will be sent the same set of psychological surveys, the medical history questionnaire, and a follow-up COVID questionnaire. The psychological surveys will be the same surveys they did during the first round, while the COVID questionnaire asks additional questions related to their experience with COVID since the clinic visit. They will not be asked to complete the personal history questionnaire the second time. This second set of questionnaires allows NIOSH to meet the study aims.

Summary statistics for demographic and lifestyle variables, variables of specific interest in each report, and relevant covariates known to be biologically important from existing literature will be generated. Regression models will be used to examine associations between risk factors and disease markers. With continuous dependent variables, change from baseline to follow-up will be modeled using the change-score (subtracting baseline from follow-up measurements) for each individual. The change-score will be the dependent variable in a general linear model where a baseline exposure variable is the independent variable. Depending on their measurement scale and the hypothesis of interest, baseline exposure variables will be included in the model either as continuous or categorical variables, leading to regression analysis or analysis of covariance (ANCOVA) models respectively.

For dichotomous outcomes (e.g., metabolic syndrome) we will compute cumulative incidence (incidence proportion) of the health outcome of interest between pre COVID to during COVID-19 and the mental health follow-up. The incidence of the health outcome will be computed after exclusion of participants who have the condition of interest at baseline (prevalent cases). This variable (presence=1/absence=0) will then be used as the dependent variable in a generalized linear model using the binomial distribution and a log link function in order to estimate the cumulative incidence as well as the incidence ratio (relative risk) associated with a categorical or continuous baseline exposure variable. Occasionally the log binomial model does not converge and fails to produce estimates. In this case, a Poisson distribution to obtain convergence along with empirical adjustment of variance estimates to correct for misspecification of the probability model will be used.

Lastly, longitudinal modeling approach for repeated measures to estimate the (1) the pattern of markers of disease overtime, (2) the effect of baseline risk factors on subclinical markers of disease, and (3) whether the pattern of markers of disease overtime depend on level of the baseline risk factor (interaction effect). PROC MIXED in the SAS System provides a very flexible modeling environment for repeated measures data. Random effects will be used to build models correlating measurements made on the same subject including subject-specific regression models and a variety of covariance and correlation structures can be specified to model the repeated measures correlation across the four time points.

Data will only be reported in aggregate. No tables will show data where the numbers are too small and could result in unintentional identification of respondents.

17. Reasons(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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