Supporting Statement A for

Prevention Research Expertise Survey

National Institutes of Health, Office of Disease Prevention (ODP)

OMB# 0925-0728, Expiration date 11/30/2020

Date: October 5, 2020

Check off which applies:

- New
- **X** Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing w/o OMB approval

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A. Justification

The Office of Disease Prevention (ODP) at the National Institutes of Health (NIH) is responsible for assessing, facilitating, and stimulating research in disease prevention and health promotion, and disseminating the results of this research to improve public health. Among the ODP's priorities is promoting the use of the best available methods in prevention research and supporting the development of better methods. One of our strategies is to help NIH Scientific Review Officers (SROs) identify experts in prevention science methods to include on their review panels. This strengthens the panels and improves the quality of prevention research supported by NIH. To identify experts in prevention science methods, we developed online survey software that allows us to collect researchers' names, contact information, and resumes, as well as allows those researchers to identify their level of expertise in a variety of prevention science methods and content areas. The data collected with this survey software populate a web-based Directory that SROs can use to identify researchers with expertise in specific prevention science methods and content areas for invitation to serve on an NIH review panels. This Directory is also shared with review staff in the other NIH Institutes, Centers, and Offices, as well as other DHHS agencies. We are seeking OMB approval for a revision to our data collection plan for the next 3 years.

A.1 Circumstances Making the Collection of Information Necessary

The NIH Office of Disease Prevention (ODP) Prevention Research Expertise Survey (PRES) program was developed to (1) identify methodologists with expertise in content areas related to prevention science, (2) identify mid- and senior- level researchers who may have an interest in serving on review panels, and (3) to enrich the existing pool of NIH reviewers by including researchers with methodological and prevention science expertise that review prevention applications.

Researchers interested in providing their information for the PRES program take the online survey and submit their identifying information, content and methodological areas of expertise, Curriculum Vitae (CV) or professional resumes, and willingness to serve on a review panel. They are included in the linked PRES Directory based on their self-reported level of expertise in methodological and prevention science content areas, as well as the information provided in their CVs, which are commonly used by researchers and other professionals to record work history and professional accomplishments. NIH Scientific Review Officers (SROs) regularly review the CVs of potential reviewers to assess their current employment, publication history, grants received, and other professional achievements, all of which provide valuable information when evaluating the appropriateness of an individual to serve on a review panel. The legislative authority allowing the collection of information from potential reviewers to determine their appropriateness to serve on grant application review panels is *42 USC Section 241: Research and Investigations General*.

The SROs will continue to have access to researchers' CVs and self-reported assessment of methodological and prevention science content expertise through the PRES Directory. PRES program staff will continue to maintain PRES and the linked PRES Directory, and these data will continue to be available to SROs as they recruit members of their review panels. In summary, PRES participants' contact information, CV, and methodological and prevention science content areas of expertise must be collected for inclusion in the PRES program.

A.2 Purpose and Use of the Information Collection

Our most recent renewal and substantive revision request was approved by OMB on November 17, 2017. Since then, we have submitted two non-substantive change requests, both of which were approved by the OMB.

The first non-substantive change request was approved on December 12, 2017. These approved modifications clarified the language on the landing page of the survey (i.e., PRES), which provides background and rationale about the survey, to (1) make it easier for returning survey respondents to understand and navigate the survey, (2) more accurately reflect the information in the Privacy Act Notifications Statement, and (3) improve the flow between concepts. It also updated and clarified the promotional language used in emails to communicate with prospective survey participants.

The second non-substantive change request was approved on December 7, 2018. These approved modifications added a question to the "Create My Profile" page of the survey about the geographic region (i.e., state, U.S. territory, or outside the U.S.) of the institution where the respondent works. This information helps SROs fulfill their official duties and comply with Federal Advisory Committee Act requirements that review panels need to be balanced by geographic region. The non-substantive change request also combined the information spread across two pages into a single page, which shortened the survey for respondents.

Since the last renewal and substantive revision request (approved by OMB on November 17, 2017), roughly 1,600 new investigators have completed PRES (for approximately 4,300 total respondents) and approximately 200 NIH SROs are using the PRES Directory. Based on feedback we received from both NIH staff and survey respondents about how to improve the survey during this three-year period, we have refined the list of existing topics and identified additional topics to include in the survey (outlined below) to help SROs better identify investigators to serve on review panels.

The purpose of this OMB clearance request is for continued collection of existing data and to update PRES in order to collect additional areas of expertise not captured in the current version of PRES. This includes updating the study design topics (2 new, 3 deleted, 3 revised), research methods topics (5 new, 12 deleted, 15 revised), content topics (7 new, 15 deleted, 9 revised), settings (1 new), and populations (1 deleted). Overall, these changes represent a net change of 16 fewer topics in PRES than what is found in the currently approved version: a total of 15 topics will be added and 31 topics will be removed; 27 topics will be revised. Using SRO feedback, we are also revising a question about NIH review experience, which will make it easier for investigators to communicate their level of interest in serving on review panels and therefore help SROs better identify investigators to serve on review panels (see Attachment 1, in which new topics are marked as "New" and revised topics are marked as "Revised"; additional details can also be found in section A.15 below). These changes will be made in the existing and already operational online software platform used for PRES and the PRES Directory in a systematic way that reduces burden on the participants and governmental costs associated with processing. We will continue to make the data available to NIH and DHHS staff who are granted accounts in the PRES Directory and are not requesting any changes to the online software platform used for PRES or the PRES Directory.

A.3 Use of Information Technology and Burden Reduction

Survey Completion via Email - Burden for Prevention Researchers. Those interested in participating in the PRES program are directed to the ODP website to complete the survey (i.e., PRES). An online survey is more

cost-effective and efficient than transmitting information between scientists and PRES program staff by mail or phone. The software program has already been developed, approved by the OMB, and is currently in use. The online survey instructs users to complete a user profile and assess their expertise in seven areas: study designs, research methods, content areas, research settings, population focus, geographic region of research, and the income category of the region/country in which the research is performed. Based on usability testing and previous approved versions of the survey, the total estimated time burden for users remains approximately 25 minutes.

Privacy Impact Assessment. In January 2015, the Privacy Impact Assessment (PIA) Form was created for the NIH ODP PRES program and submitted to and signed by the NIH Senior Official for Privacy (see Attachment 2). The PIA included the development of a database of respondents (i.e., the PRES Directory) for the PRES program. The online survey software saves the information submitted by respondents to the linked PRES Directory, which can only be accessed using an official government-issued HHS ID Badge/PIV Card by authorized NIH and DHHS staff for whom an account has been created in the PRES Directory. The PRES Directory includes applicants' names; email address; academic institution, position, and state; areas of expertise; as well as their NIH eRA Commons ID and CV, if they chose to include it.

A.4 Efforts to Identify Duplication and Use of Similar Information

PRES requires each researcher to create a profile with basic contact information and complete the online survey; it also provides the option to submit a CV. Some of the information gleaned from researchers' CVs might also be available through university websites, IMPACII, social media sites, professional association websites, or via telephone or email contact with the applicant. However, some of these sources are used inconsistently or may include outdated or incomplete information, which can introduce variations into the way in potential reviewers are evaluated. When respondents complete the online survey and upload a CV, it standardizes the process and provides SROs with authoritative information in one place where they can find mid- and senior- level methodological experts for review panels. The information about the respondent's level of expertise for content areas and methodological topics that is gathered through the PRES program is not available from any other source or agency.

A.5 Impact on Small Businesses or Other Small Entities

Researchers from small organizations are eligible to complete the online survey, but participation is voluntary. The information being requested of all prevention researchers has been held to the minimum required for evaluation of appropriateness for inclusion in the PRES Directory and NIH review panels.

A.6 Consequences of Collecting the Information Less Frequently

Frequency of Survey Completion. Prevention researchers complete the survey and upload their CVs only once. If those researchers gain more expertise, change jobs, and/or get new contact information after completing the survey, they can update their information using the same online mechanism by signing into their profile and updating any pertinent sections (including their profile and specific areas of expertise).

Consequence of not collecting information. As described in Section A.4, some of the information gleaned from researchers' CVs might also be available through university websites, IMPACII, social media sites, professional association websites, or via telephone or email contact with the applicant. However, some of these sources are used inconsistently or may include outdated or incomplete information, which can introduce variations into the way in potential reviewers are evaluated. When respondents complete the

online survey and upload a CV, it standardizes the process and provides SROs with authoritative information in one place where they can find mid- and senior- level methodological experts to serve on review panels.

The online survey and CV also greatly reduce staff time that would otherwise be needed to conduct detailed online searches for information on each potential reviewer. Given the high volume of prevention researchers, it is more cost-effective to ask PRES participants to provide their CVs and information about their degree(s), training, methodological and content area expertise, and willingness to serve on a NIH study section, than it is to hire staff to conduct individualized online searches to verify the qualifications of each researcher. It also prevents the issue of staff potentially using the wrong information from an online search for researchers with similar names. Finally, providing all information at the time of the survey submission reduces the number of times that ODP PRES program staff or SROs need to contact the PRES participant to verify or to request additional information.

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

The software for PRES and the linked PRES Directory fully complies with all guidelines stated in 5 CFR 1320.5. No special circumstances are applicable.

A.8.1 Comments in Response to the Federal Register Notice

This proposed information collection published in the Federal Register on August 6, 2020, Vol. 85, No. 152, pages 47805-47806, and allowed 60 days for public comment. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

Consultation with advisors regarding the program.

The plan to develop the PRES program was discussed with and approved by the Associate Director for Prevention and Director of the NIH Office of Disease Prevention, Dr. David M. Murray. The ODP conducted extensive consultations with several prevention researchers, senior-level methodologists, SROs, and NIH Program staff when the PRES program was first developed in 2014 and again for the last full renewal and substantive revision in 2017. In preparation for this renewal and revision request, the ODP conducted additional consultations about the data collection tool (i.e., PRES), user satisfaction, and potential changes to PRES (see Attachment 3). As outlined below, the requested revisions to the data collection for PRES are based on feedback both from NIH staff who used the PRES Directory and from survey respondents who completed the survey since the last full OMB approval in November 2017.

To assess the utility of the PRES program to NIH SROs, the ODP consulted with Dr. Valerie Durrant, Director, Division of AIDS, Behavioral and Population Sciences, NIH Center for Scientific Review; Dr. Ruth Grossman, Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences; the staff of the NIH Office of Dietary Supplements; and the staff of the NIH Office of AIDS Research. Their review and feedback were based on use of the PRES program during the previous approval period, as well as first-hand knowledge of the types of research projects submitted to the NIH. Their recommendations include adding new topics and refining language about NIH review experience to help SROs better identify researchers to serve on review panels. This feedback has been incorporated into the current revision request for the survey (see Attachment 1).

To gather participant feedback about the survey, respondents are given the opportunity in two sections of the survey (Step 3 - Research Methods and Step 4 - Content Topics) to propose new topics for consideration in future versions of the survey. The ODP tabulated and evaluated all the suggestions submitted by respondents since the last full OMB approval in November 2017 and compared these suggestions to the topics already included in the survey to eliminate any overlap or redundancy. Based on this review, the ODP has incorporated several new topics and revised the wording of others to improve clarity and accuracy in the current revision request (see Attachment 1). Survey respondents will continue to have the opportunity to propose new topics over the course of the next approval period and the ODP will review suggestions on a regular basis in order to assess the need for changes to the survey in the future.

A.9 Explanation of Any Payment of Gift to Respondents

The opportunity to participate in the PRES program is voluntary. No compensation is provided for completion of the survey.

A.10 Assurance of Confidentiality Provided to Respondents

System of Record. The Privacy Act Memo Systems of Record Notice that covers the information collection is 09-25-0036, titled, Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH published September 26, 2002 vol. 67 pgs. 60742-60784 (See Attachment 4).

To maximize the protection of their personal information, investigators are asked to complete a user profile that includes creating a username and password before they take the survey. Respondents' CVs and additional identifying data is saved on a secure website (i.e., PRES Directory) hosted by the NIH Office of Information Technology (OIT). This data is accessible only by select DHHS staff with PIV cards who have been granted permission and had an account created for them in the PRES Directory by ODP PRES program staff. ODP PRES program staff work with OIT to grant select DHHS staff access to the PRES Directory and deletes permissions for access if an employee leaves their position. In addition to needing an account in the PRES Directory, DHHS staff are only able to log into the PRES Directory with their government-issued HHS ID Badge/PIV cards while on the official, secure VPN connection.

Since PRES was originally approved for use by OMB in late 2015, the website has included a statement regarding privacy as part of the introduction to completing the survey. This statement indicates that the information provided will be kept private to the extent allowed by law and not disclosed to anyone but the ODP PRES program staff and DHHS staff who evaluate submissions except as otherwise required by law. We also included in the introduction to the survey a statement that clearly states that 42 USC Section 241: Research and Investigations General provides legislative authority to collect information for the PRES program, that participation in the program is strictly voluntary, and that no consequence exists for choosing not to participate.

Prevention Research Expertise Survey and Electronic Directory. The information retained in the searchable Directory includes investigators' names, job title, email address, and institution name and location (state only). We do not collect date of birth, social security number, home address, race, ethnicity, or gender. We have chosen not to collect race and ethnicity data two reasons: (1) the information provided by PRES respondents is made available to SROs for the purpose of potential inclusion in study review panels. We want to avoid potential bias as well as the appearance of bias based on race/ethnicity in their selection process. (2) When investigators create NIH eRA Commons accounts, they have the option to choose whether or not to disclose information regarding race and ethnicity. Access to those data is limited to

protect the applicant. However, when data summaries by race/ethnicity are needed for program evaluation purposes, only approved personnel with specific responsibility for data summaries can access those data. ODP PRES program staff do not have access to sensitive data from individual PRES participants.

The information collected via the online survey is the same information used by SROs to vet all other potential review panel members. In the course of their daily job duties, SROs gather information on potential reviewers including education and job title, professional accomplishments, publications, and any other information that represents the expertise of the potential reviewer. Summaries are periodically tallied in an aggregate form for administrative use regarding the institutions at which investigators are employed. Names of individual investigators are not included in these summaries. The information from participants is not used for research or survey purposes.

A.11 Justification for Sensitive Questions

Sensitive information is not needed to determine each researcher's fit with a prevention-focused review panel and will therefore, not be collected.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Annual Hour Burden. Based on data and analytics for participation in PRES since the last approved OMB renewal and substantive revision in November 2017, it appears that the rate of participation in the survey is approximately 50 new investigators per month (i.e., investigators completing the survey for the first time). Assuming a constant rate, the PRES program should receive approximately 600 new investigator survey completions per year. Using an estimated response time of 25 minutes per survey, the annual burden for survey respondents is 250 hours. Section A.3. above provides additional details regarding this estimate. Based on the same set of PRES participation data and analytics over the past three years, we expect roughly 1,000 returning investigators (those who have completed previous versions of the survey) will return and update their information per year. Returning investigators are invited to update their information based on the additional topics added (discussed in sections A.2. and A.15.). Using an estimated response time of 10 minutes per returning investigator to update their responses in the revised version of the survey, the annual burden for those respondents is 167 hours. Please see Table 12-1 below for details.

Table 12-1 Estimated Annualized Burden Hours

Type of Respondents	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Annual Burden Hours**
New Investigators	600	1	25/60	250
Returning Investigators to update information	1,000	1	10/60	167
Total		1,600		417

A.12-2 ANNUAL COST TO RESPONDENT

According to the Bureau of Labor Statistics May 2019 National Occupational Employment and Wage Estimates for the United States, the mean hourly wage for a Life Scientist is $42.68. This number was used to calculate the annualized costs to respondents. Based on an estimate of 1,600 participants per year, and a total annual burden of 417 hours, we estimate the total respondent cost to be $17,797.56.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Investigators	417	$42.68	$17,797.56
TOTAL	417		$17,797.56

*Bureau of Labor Statistics: The Life Scientist wage rate was obtained from https://www.bls.gov/oes/2019/may/oes_nat.htm#19-0000. Occupation title "Life Scientists," occupation code 19-1000.

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

There are no additional cost burdens to respondents other than those described in section A.

A.14 Annualized Cost to the Federal Government

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
PRES Administrator/Support	GS13-07	$119,006	25%		$29,752
Contractor Cost					
PRES Contract Total					$108,000
Travel					
Other Cost					
Total					$137,752

*the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/PHL.aspx

A.15 Explanation for Program Changes or Adjustments

This is a revision to the existing PRES program. There are no plans to publish any of the information collected from participants. Periodic summaries of the information collected (e.g., number of participants by institution, state, or region) will be for internal use only. In those cases, information will be reported in aggregate form without individual identifiers.

Since the last renewal and substantive revision request (approved by OMB on November 17, 2017), roughly 1,600 new investigators have completed PRES (for approximately 4,300 total respondents) and approximately 200 NIH Scientific Review Officers (SROs) are using the PRES Directory. Based on feedback we received about how to improve the survey from both NIH staff and survey respondents during this three-year period, we have refined the list of existing topics by removing unclear or rarely used topics, revising the wording of some topics to increase clarity and accuracy, and identifying additional topics to include in the survey (outlined below). These changes are intended to make the survey simpler to take by the respondents and to help SROs better identify investigators to serve on review panels.

Therefore, the purpose of this OMB revision request is to collect additional data from investigators using the existing procedures, format, and online software platform for PRES and to make that data available to NIH and DHHS staff who are granted accounts in the PRES Directory. The changes to the survey and the additional information we seek to collect include updating the study design topics (2 new, 3 deleted, 3 revised), research methods topics (5 new, 12 deleted, 15 revised), content topics (7 new, 15 deleted, 9 revised), settings (1 new), and populations (1 deleted). Overall, these changes represent a net change of 16 fewer topics in PRES than what is found in the currently approved version: a total of 15 topics will be added and 31 topics will be removed; 27 topics will be revised. Using SRO feedback, we are also reducing the number of possible responses from 6 to 5 for a question about NIH review experience. By revising and streamlining the wording of one of the responses, it will be easier for investigators to communicate their level of interest in serving on review panels and therefore help SROs better identify investigators to serve on review panels (see Attachment 1, in which new topics are marked as "New" and revised topics are marked as "Revised," and below for more details on the revisions).

These changes will be made using the existing and already operational PRES online survey in a systematic way that reduces burden on the participants and governmental costs associated with processing.

Changes to the current online survey include the addition, deletion, and revision of topics listed below:

Study Design Topic:

2 New topics – Case Control Studies (e.g., Unmatched, Matched, Nested); Cohort Studies (e.g., Prospective, Retrospective)
3 Deleted topics – Cross-Sectional Designs; Factorial Designs; Fractional Factorial Designs
3 Revised topics – Clinical Trial Designs (Individual Randomization); Mixed- or Multi-Method Designs for Qualitative and Quantitative Data; Stepped-Wedge Designs

Research Methods:

5 New topics – Basic Research; Data Harmonization; Multiphase Optimization Strategy (MOST); Preclinical Studies; Qualitative Methods
12 Deleted topics – Alternative/Authentic Assessment; Complier Average Causal Effect (CACE) Analysis; Imaging (fMRI, MRI, CT, Ultrasound, EEG, MEG, ECG, PET, X-ray, etc.); Individual Person-Level Meta-Analysis; Integrative Data Analysis; Item Response Theory; Measurement Theory and Methods (EFA, CFA, etc.); Microsimulation Methods; Migration Analysis (Attrition, Emigration, etc.); Natural Language Processing; System Dynamics; Systems Engineering Methods
9 Revised topics – Biomarker/Risk Factor Analysis or Validation; Data Mining/Big Data; Electronic Health Records (EHRs); General Linear Modeling (e.g., Regression, Multivariate Analysis); Generalized Linear Modeling (e.g., Logistic, Poisson, Gamma); Machine Learning and Artificial Intelligence; Meta-Analysis; Methods for Analysis of Intensive Longitudinal Data; Missing Data Methods (e.g., Imputation, Full Information Maximum Likelihood); Mixture Models (e.g., Growth

and Regression Mixture Models); Mobile Health (mHealth) and Other Health Technologies; Mixed-Model/Multilevel/Hierarchical Regression; Power Analysis/Sample Size Estimation; Propensity Score Methods; Psychometric Methods and Measurement Theory (e.g., Item Response, Factor Analysis)

Content Topics:

7 New topics – Antimicrobial Resistance; Gastrointestinal Diseases; Health Education; Pain and Pain Management; Precision Medicine; Radiation Exposure or Injury; Team Science

15 Deleted topics – Allergies; Asthma and Other Respiratory Diseases; Communication Disorders, Including Hearing, Vision, Speech; Dementia; Firearms; Health Care Delivery; Healthcare-Associated Infections; Immunology; Kidney Disorders; Metabolomics; Microbiome; Musculoskeletal Disease; Pneumonia; Public Health Preparedness; Skin Diseases

9 Revised topics – Alzheimer's Disease and Other Dementias; Arthritis/Musculoskeletal Disease; Genetics/Genomics; Health Services Research and Health Economics; Influenza/Pneumonia; Lung Disease (Emphysema, COPD, Asthma); Sleep and Sleep-Related Disorders; Tobacco and Electronic Nicotine Delivery Systems; Vaccine Development and Distribution

Settings:

1 New topic – Prisons/Correctional Facilities

Populations:

1 Deleted topic – White Americans

NIH Review Experience

Revised response: "I am not currently reviewing applications but would be interested in being an ad hoc or appointed member of a study section."

We are estimating a lower level of burden (1,600 respondents and 417 annual burden hours) in this revision request than we did in our last approved OMB renewal and substantive revision in November 2017 (4,120 respondents and 1,550 burden hours) – see tables below. As outlined in section A.12.1. above, the reduction is based on the ODP's review of data and analytics for PRES participation during the past three-year period (2017-2020), which indicates the number of new investigators who complete the survey for the first time has been approximately 50 per month. Assuming a constant rate, the PRES program should receive approximately 600 new investigator survey completions per year. Using an estimated response time of 25 minutes per survey, the annual burden for new survey respondents is 250 hours. Section A.3. above provides additional details regarding this burden hour estimate. We also expect roughly 1,000 returning investigators (those who have completed previous versions of the survey) will return and update their information per year. Using an estimated response time of 10 minutes per returning investigator to update their responses, the annual burden for those respondents is 167 hours. This equals an estimated total of 1,600 respondents annually and 417 annual burden hours for the current revision request.

Annual burden hours for 2017 OMB-approved PRES data collection tool: 1,550

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Investigators	3,120	1	25/60	1,300
Returning Investigators to update information	1,000	1	15/60	250
Total		4,120		1550

Revised annual burden hours for current OMB revision request for PRES data collection tool: 417

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
New Investigators	600	1	25/60	250
Returning Investigators to update information	1,000	1	10/60	167
Total		1,600		417

A.16 Plans for Tabulation and Publication and Project Time Schedule

The proposed revisions to the online survey (i.e., PRES) are highlighted in Attachment 1.

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Letters sent to respondents	Ongoing (respondents contacted every 24–36 months)
Field questionnaire	Entire duration of OMB approval for project
Completed field work	Ongoing
Validation	Ongoing
Analyses	Ongoing
Publication	N/A

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

Not applicable, as we are not requesting approval to not display the expiration date for OMB approval.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable, as we are not requesting an exception to certification for the Paperwork Reduction Act.