

Supporting Statement A For:

Awareness and Beliefs about Cancer (ABC) Survey (NCI)

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Yellow highlights indicate revisions to this project from the previously approved submission in 2013.

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A. JUSTIFICATION

This is a request for a revision of the, “Awareness and Beliefs about Cancer (ABC) Survey.” The objective of the proposed study is gather data about American adults’ awareness and beliefs about cancer. The ultimate goal is to determine how individuals’ perceptions of cancer may influence their decisions to report signs and symptoms to health care providers, perhaps affecting the disease stage of diagnosis and the effectiveness of treatment. This project also offers an opportunity to compare data from the United States to international data. Culturally and language-adapted versions of this instrument have been administered in eight other countries. Data may inform theory-based, multilevel behavioral interventions that promote symptom reporting and early diagnosis of cancer. The survey instrument incorporates factors such as demographic variables, beliefs, and perception of access to health care in the context of decision making. The project asks specific questions about screening and care seeking behaviors that will inform understanding of preferences for participation in health care decisions and will generate insights to improve cancer survival. A representative sample (approximately 1,500 respondents) of the population aged 50+ will be surveyed using a standardized measure of cancer awareness and beliefs. This request is to include cellphone-only households in the ABC survey; the original request was to survey only landline households.

A.1 Circumstances Making the Collection of Information Necessary

Authorization to Collect Data

The Division of Cancer Control and Population Sciences (DCCPS) aims to reduce the risk, incidence, and deaths from cancer as well as enhance the quality of life for cancer survivors through a program of genetic, epidemiologic, behavioral, social, and surveillance cancer research. Within DCCPS, the Behavioral Research Program (BRP) initiates, supports, and evaluates a comprehensive program of research ranging from basic behavioral research to the development, testing, and dissemination of interventions in areas such as tobacco use, screening, dietary behavior, and sun protection. The Public Health Service Act Sections 410 (42 USC § 285) and 413 (42 USC § 285a–2) authorizes DCCPS to collect information for research and information dissemination purposes. Additionally, it grants to the National Cancer Institute director, in the organization’s public information and education role, the provision of information

and programs that will raise awareness of risk reduction, early detection, and options for managing cancer and improving survival.

Project's Relevance to NCI

The Awareness and Beliefs about Cancer (ABC) Survey is proposed by the Process of Care Research Branch (PCRB), a branch housed within BRP. PCRB focuses on behavioral issues in health care settings across the cancer continuum, from prevention and screening through diagnosis and treatment. Among the specific branch foci relevant to this project are:

- Theory-based multilevel behavioral interventions in screening, diagnosis, and recruitment to clinical trials;
- The role and relative importance of individual and contextual factors in decision making including consideration of age, ethnicity, organizational setting, and provider-patient interaction; and
- Understanding (of patient's views of) of health care behaviors (screening, lifestyle, genetic testing, treatment choices) and preferences for participation in health care decisions

These three focal points are addressed by the project. First, the project proposes to gather data that may inform theory-based, multilevel behavioral interventions that promote symptom reporting and early diagnosis of cancer. Second, the survey instrument incorporates factors such as demographic variables, beliefs, and perception of access to health care in the context of decision making. And third, the project asks specific questions about screening and care seeking behaviors that will inform understanding of preferences for participation in health care decisions.

This survey has three important aims to:

1. Identify the role US patients play in early detection of cancer based on symptom reporting;
2. Suggest points of intervention to improve early detection of cancer; and

3. Compare US patients to those in other cultures and health care systems, which will also shed light on system effects on early detection and suggest points of intervention beyond the patient.

Project Background

A representative sample of the population aged 50+ will be surveyed using a standardized measure of cancer awareness and beliefs (Simon et al., 2012). This process will explore the association between cancer awareness and behavior and compare cancer awareness and beliefs between the United States and other countries that have used this survey instrument. Specifically, data collected in this study will inform understanding of how people recognize signs and symptoms of cancer and will generate insights to improve cancer survival. Cancers found and treated at earlier stages may result in extended life, less intensive therapies (Henley, King, German, Richardson, & Plescia, 2010), lower costs (Campbell & Ramsey, 2009; Taplin et al., 1995), and less emotional and psychological burden on patients (Simon, Thompson, Flashman, & Wardle, 2009; Vodermaier, Linden, MacKenzie, Greig, & Marshall, 2011), compared with later-stage cancers (**Attachment 1**).

Value to NCI

These data about cancer awareness and beliefs are essential to enable NCI and the extramural community to understand the role of patients in early detection of cancer and therefore to design evidence-based interventions to increase early recognition and detection of cancer.

The project offers an additional opportunity to compare data from the United States to international data. Culturally and language-adapted versions of this instrument have been administered in eight other countries. The international comparison not only provides an

opportunity for collaborations with other researchers who are seeking ways to intervene in cancer care but also provides a theory-building opportunity. With multiple datasets available, the relationship of culture and context in cancer awareness, beliefs and care seeking behaviors can be examined in great detail. The value of international comparison has been recognized and manifested in many ongoing programs within the Division, including HINTS Chinese (Health Information National Trends Survey), SEER-Medicare comparisons to data from Ontario, Canada, and the proposed adaptation of the Automated Self-Administered 24-hour Dietary Recall (ASA24) tool for use in Canada and the United Kingdom (National Cancer Institute, 2012).

The data collection and proposed analysis offer many advantages. First, the methodology to be employed is a well-vetted approach for assessing the United States' (U.S.) diverse population's attitudes and beliefs. For a representative sample, the methodology includes contacting both landline and cellphone-only households in the U.S. Second, the questionnaire and analytic plan are grounded in health behavior theory and have been validated in other countries. Third, the survey will be similar to surveys recently conducted in eight other countries¹, meaning results can be compared to examine national and cultural differences in cancer awareness and beliefs. Finally, this study will provide insights to be used immediately for intervention design and in the future for more research.

Recent literature indicates that the percentage of older Americans living in households without a landline is growing quickly. The most recent information indicates that almost 26% of adults aged 45-64 live in households without a landline.² This raises concerns about the

¹ The countries include Australia, Sweden, Denmark, Norway, England, Northern Ireland, Wales and Canada.

² Blumberg, S. and Luke, J. Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, January-June 2013. National Center for Health Statistics, Centers for Disease Control and Prevention. Released 12/2013. <http://www.cdc.gov/nchs/data/nhis/earlyrelease/wireless201312.pdf>

representativeness of a landline-only telephone survey. Thus this revision request is to include cellphone-only households in the ABC survey, in addition to the already approved landline households. To date, no information collection has begun because it is important to collect both the landline and cellphone-only household data at the same time. Concurrent data collection helps to maintain comparability of the landline and cellphone data, increasing the likelihood that the two groups can be combined in one larger, dataset.

Additionally, due to budget constraints, a slightly smaller sample is being proposed thus maintaining the same costs to the government as the original submission. Although the number of participants would decrease by 500, the total estimate of burden hours would increase (see Section A. 12). This increase reflects the need to contact and screen more people to reach cell phone-only participants.

A.2 Purpose and Use of the Information

Overview of Survey

The screener will introduce respondents to the survey and assess their eligibility – primarily, are they 50+ years of age. The additional questions posed to cell phone participants are necessitated first by a concern for their safety (“are you currently driving?”) and second by the different approach needed to screen cell phone users rather than households(see **Attachment 2, page 4**).

The survey will use a telephone interview-based measure of cancer awareness and beliefs (Awareness and Beliefs about Cancer (ABC); see **Attachment 3**). These items explore awareness of cancer symptoms and risk; beliefs about cancer, cancer screening, and use of health care services; behaviors related to cancer screening and symptom reporting; and demographic characteristics of survey respondents. The measure was developed by an eight-country team of researchers in the International Cancer Benchmarking Partnership; the United States was not

involved in the partnership. Cancer Awareness (“Awareness”) items were adapted from questions in the Cancer Research United Kingdom Cancer Awareness Measure (CAM). Cancer Beliefs (“Beliefs”) items were developed from theoretical constructs which have been shown in the literature to predict relevant intentions or behaviors (e.g. screening uptake). “Awareness” and “Beliefs” items include questions about knowledge of symptoms; anticipated delay in seeking medical help; awareness that risk of cancer increases with age; access to primary care including perceived barriers; beliefs about cancer in general, including prognosis; beliefs about benefits of early symptomatic presentation and early diagnosis of cancer; cancer screening beliefs and behavior; and cancer risk factors awareness.

Demographic information such as age, sex, race/ethnicity, education, region of residence and ethnicity will examine differences in responses to questions about cancer awareness and beliefs between demographic groups. This information will also allow assessment of the representativeness of the sample and the comparability of the samples across jurisdictions. The measure will include a question about language spoken at home, because people who do not speak English at home may have different cancer awareness and beliefs from those who do. The measure also includes items about personal experience with cancer, which may influence awareness and beliefs. The survey instrument has been adapted to reflect American English vernacular. There were minor wording changes to streamline the conversation (deleted some phrases) and changed wording so it is consistent with English vernacular from the United States (in Questions 6, 13, QM Introduction, and 41). Additionally, pages 15 to 18 have added landline and cell-phone only questions.

Use of the Information

The principal users of the collected data will be program directors and extramural scientists working with the Behavioral Research Program within the National Cancer Institute. Program directors rely on such data to set agendas and guide development of program announcements, meetings, and special journal issues that spotlight important research needs in particular areas. Extramural scientists will use these data to support applications for future research on early detection. Secondary users will be international researchers who will be able to compare United States' data to other countries. Downstream users of the information will be public health program planners who will use findings as they develop high quality interventions to address factors related to cancer prevention, treatment, and survival.

The information collected will be used for the following purposes to:

- Identify needs for research program areas, including but not limited to developing program announcements, writing manuscripts for peer review publications and national conferences, and creating collaborations;
- Inform other surveys by highlighting questions or series of questions that should be included on future instruments to advance the science;
- Guide interventions by identifying the factors associated with optimal and non-optimal cancer awareness and behavior;
- Provide for international comparisons and benchmark future trends that will further help understand the role of culture and system in influencing cancer awareness, beliefs, and behaviors and
- Drive policy to improve cancer awareness and assess policy impact; tackle negative beliefs about cancer; and benchmark future trends and assess policy impact. Results from the study will take the form of publications in peer-reviewed journals and potential for funding or program announcements.

The insights gained from this survey's analyses will inform the nation's prevention efforts. First, the findings will help develop strategies for meeting Healthy People 2020 objectives in cancer control.³ Among the objectives are the reduction of mortality from cancer,

³ <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=5>

the increase in 5-year survival rates, and improvement in quality of life for cancer survivors. The project's findings would identify appropriate points of intervention to address current knowledge, attitudinal, and behavioral barriers to seeking care when cancer is more treatable. The survey's inclusion of socio-demographic variables may reveal population subgroups or characteristics to which interventions can be tailored and made more effective.

Second, the project's findings can contribute to novel and evolving health organization models that emphasize primary and secondary prevention over tertiary care. The Accountable Care Act (ACA) encourages prevention in several ways, including wellness visits for older adults, cancer screening benefits,⁴ and Accountable Care Organizations' quality care measures. Once the ACA's benefits are fully implemented, many of the care-seeking access barriers will be removed. However, for early detection goals to be realized, efforts must address the other barriers to care-seeking. The ABC's findings will give agencies' and policy makers' data with which they can identify and address critical psycho-behavioral obstacles to care-seeking.

A.3 Use of Improved Information Technology and Burden Reduction

Data will be collected using computer-assisted live telephone interviews (CATI) and maintained digitally. This efficient method of interviewing allows the interviewer to follow a script that can be customized based on respondents' answers to questions. The method saves time and money, reduces respondent burden, and increases accuracy in and fidelity between responses and data coding.

After a consultation with the NCI Privacy Act Coordinator, a Privacy Impact Assessment (PIA) has been drafted and is under review at the NCI level (**Attachment 4**).

⁴ <http://www.healthcare.gov/news/factsheets/2010/07/preventive-services-list.html>

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

Compelling research into the association between cancer beliefs, awareness of symptoms/signs, and care seeking behavior has been conducted albeit with limited methodologies (e.g. small sample size, qualitative, and observational studies). A large population dataset like the one proposed here would provide the necessary statistical power to test hypotheses and reveal significant relationships between beliefs and predicted health care seeking behavior.

The ABC survey is proposed to collect information once that is unique, nationally representative data about awareness of cancer warning signs and symptoms, anticipated delay in seeking medical help, and beliefs about the importance of seeing a doctor for early symptoms of cancer. Our research indicates that no nationally representative survey has been conducted in the US to learn about these topics. There are studies with items that are similar to the items in the ABC survey, but that do not quite capture the same data. For example, in 2005, the Health Information National Trends Survey (HINTS) included a series of items assessing awareness of lung, colon, and skin cancer symptoms. These items have not been repeated since 2005 and were limited to those three specific cancers; the items were open-ended, which meant only symptoms respondents were already aware of would be elicited. The ABC survey includes a list of symptoms that respondents will be asked to describe as related or not related to any cancer. Likewise, neither the National Health Interview Survey (NHIS) nor the Behavioral Risk Factor Surveillance Survey (BRFSS) has included awareness of symptoms or anticipated delay in help seeking. These types of items are necessary as part of the ABC survey for providing context in which to understand the primary areas of interest and are not considered as unnecessary overlap.

A.5 Impact on Small Businesses or Other Small Entities

No small entities will be involved in this survey. All respondents will be individuals who participate voluntarily.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time collection.

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

The project fully complies with the guidelines of 5 CFR 1320.5.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on June 19, 2013 (Vol. 78, P. 36788). Requests for information, questions, and comments were received from: Karen Kaplan (Prevent Cancer Foundation), Stephanie Nutt (LIVESTRONG FOUNDATION), and Jean Public (**Attachment 5**). All requests were responded to prior to OMB review of the submission.

Many people have consulted in the development and planning this survey and information collection (**Attachment 6**). The survey was proposed and developed in collaboration with Professor Jane Wardle, University College London, co-Chair of the International Cancer Benchmarking Partnership Central Team; and also with Professor Jerry Suls, Iowa State University. Dr. Wardle leads the related international ABC effort and is the main point of contact with the group of eight countries that have collected parallel data. She is an internationally recognized expert in cancer screening and other primary care-related behaviors affecting cancer diagnosis. Dr. Wardle is not aware of any comparable data already being collected in the US. Dr. Wardle strongly endorses the survey methods proposed for this US ABC survey.

Dr. Suls is a Social Psychologist with expertise in attitudes that influence symptom reporting, in cancer and other health domains (particularly heart disease). He was on an Intergovernmental Personnel Act (IPA) assignment to the Behavioral Research Program and has now returned to his home institution, the University of Iowa. Dr. Suls is also not aware of any US data collection on the full range of topics included in the proposed ABC survey. He will continue his involvement in this project through the questionnaire translation and data analysis and publication phases. Drs. Wardle, Kobrin, and Suls have consulted frequently over the past year to discuss the unique opportunity presented by fielding a US version of the ABC survey for comparison with the other countries' data.

Dr. Richard Moser, in the Science of Research and Technology Branch, and Dr. Kelly Blake, in the Health Communication and Informatics Research Branch (both of the NCI's Behavioral Research Program), have been consulted about the proposed survey. Dr. Moser is a psychologist with expertise in surveillance design and analysis and is part of the management team for the Health Information National Trends Survey (HINTS). HINTS is a nationally representative survey which regularly surveys Americans' attitudes, beliefs, and behaviors regarding cancer information and cancer prevention and control behaviors. Dr. Moser does not see overlap between HINTS and the proposed ABC survey and is very enthusiastic about the unique data collection proposed. He and Dr. Kobrin work closely together and Dr. Moser will continue to consult through the survey translation and data analysis phases.

Dr. Kelly Blake is an expert in health communication. She has consulted on the development of a small number of items to be added for the US ABC survey, items designed to highlight differences between US and other countries' attitudes towards cancer symptoms. Dr.

Blake does not know of another survey collecting the data proposed for the ABC survey. Dr. Blake will continue to consult through the survey translation and data analysis phases.

A.9 Explanation of Any Payment or Gift to Respondents

Respondents will not be offered any gift or incentive for their participation.

A.10 Assurance of Confidentiality Provided to Respondents

Participants will be informed that all information will be kept secure and secure to the extent permitted by law. It will be stated that participants will not be asked to give any personal data that would enable their names being matched to individual participants. The data will not contain any direct personal identifiers (name/address etc.), but will contain some personal information e.g. age, ethnicity. Data held will be password protected. All data will be collected and stored in accordance with NIH human subjects' policies.

This research will be carried out using a telephone interview. The interviewer "script" (see **Attachments 2 & 3**) provides verbal information about the study and follows a consent protocol. Participants will be informed about the aims and objectives of the study as a part of the consent and recruitment process and they will be aware of the topics that will be discussed before the research survey commences. Agreement to conduct the interview is considered consent. However, if any of the participants becomes distressed or anxious during the telephone interview, he/she will be asked whether he/she would like to have a break or withdraw from the study without penalty. Participants will be directed to further sources of information about cancer from NCI, including 1-800-4-CANCER and cancer.gov.

The NCI Institutional Review Board (IRB) has approved this project. In addition, it has been reviewed and approved by the Ethics Board of the University College London. See **Attachment 7** for all IRB approvals. The NIH Privacy Act Officer has reviewed this information

and determined that the Privacy Act does apply (**Attachment 8**). The applicable NIH Privacy Act Systems of Record Notice is 09-25-0200, “Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/OD” published on 9/26/2002.

A.11 Justification for Sensitive Questions

Personally identifiable information (PII) will be collected and includes age, sex, race/ethnicity, education, and region of residence. The information collection does contain questions that could be considered sensitive questions discussing the topic of cancer which can be distressing for some people. Moreover, the prevalence of cancer in the general population is high (one in three people), thus it is likely that many participants may have friends or family members who have been diagnosed with cancer. It is not anticipated that this study will cause particular discomfort and every effort will be made by the researchers to ensure that interviewer is sensitive to these issues. Participants will be aware of the topics before the study commences and if they decide to take part, they will be entirely free to withdraw from the research at any time. The script clearly describes the topic of research and it is not anticipated that people who decide to take part will be caused any additional distress or discomfort. If a participant becomes distressed by the discussion, the researcher will offer to stop the interview and reiterate the participant’s right to withdraw from the research. Participants will also be directed to 1-800-4-CANCER and to contact NIH staff directly.

A.12 Estimates of Annualized Burden Hours and Costs

To date, information collection has not begun yet due to the need to collect the information from the landline and cellphone-only households within the same time frame. The telephone screener will take approximately 5 minutes to complete and the telephone interview will take approximately 20 minutes to complete. **It is estimated that approximately 14,000**

respondents will complete screening and that approximately 1,500 will complete the survey.

This information is planned to be collected within one year and the total and annual estimate of burden is estimated to be 1,667 hours (Table A.12-1).

Table A.12-1 Estimates of Annual Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Screener (Attach 2)	General Public	14,000	1	5/60	1,167
Survey (Attach 3)	Adults 50+ years old	1,500	1	20/60	500
Total					1,667

The annualized cost is calculated with a wage rate of \$22.33 per hour for the 1,667 burden hours are estimated to be \$37,224.11.

Table A.12-2 Annualized Cost to Respondents

Survey Instrument	Annual Burden Hours	Hourly Wage Rate*	Total Cost
Screener	1,167	\$22.33	\$26,059.11
Survey	500	\$22.33	\$11,165.00
Total			\$37,224.11

*Hourly Wage Rate obtained from Bureau of Labor Statistics, “All occupations” occupation code 00-0000, http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000.

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

There are no costs to respondents beyond those presented in section A.12.

A.14 Annualized Cost to the Federal Government

The largest cost to the federal government is to pay a contractor and it is estimated to be \$150,000 to conduct the study and deliver data files. NCI costs are based entirely on labor. It is estimated that the study will require about 0.66 FTE total effort by federal health scientist administrators and a research psychologist at the GS14 level, totaling \$81,820.42 (based on the OPM 2014 Salary Table for Greater Washington Area). The government expenses are related to directing contractors, overseeing and solving problems as they arise, developing survey items, supervising data collection, data coding, data cleaning, data analyses, and preparation of manuscripts and presentations. Table 14-1 estimates the estimated annual cost to the Federal Government to be \$231,820.42.

Table A.14-1 Annual Cost to the Federal Government

Contractor Costs	\$150,000
NCI Personnel - Health Scientist Administrator Grade 14 Step 5 (.22 X 120,429)	\$26,494.38
NCI Personnel - Research Psychologist Grade 14 Step 6 (.22 X 123,970)	\$27,273.40
NCI Personnel - Health Scientist Administrator Grade 14 Step 7 (.22 X 127,512)	\$28,052.64
Grand Total	\$231,820.42

A.15 Explanation for Program Changes or Adjustments

This is a revision due to program change which is the result of action by NCI. This revision expands the methodology to include cellphone-only households in the ABC survey so as to gain a representative sample. This is in addition to the already approved landline households. To date, no information collection has begun because it is important to collect both the landline

and cellphone-only household data at the same time. Concurrent data collection helps to maintain comparability of the landline and cellphone data, increasing the likelihood that the two groups can be combined in one larger, dataset.

Additionally, due to budget constraints a slightly smaller sample is being proposed thus maintaining the same costs to the government as the original submission. Although the number of participants would decrease by 500, the total estimate of burden hours would increase. This increase reflects the need to contact and screen more people to reach cell phone-only participants. This is a request for 1,667 hours, which is an increase of 333 hours from the previous approval (a total of 1,334 burden hours).

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

Statistical analysis will be conducted to explore the relationships among cancer awareness, beliefs, and behavior. All data will be analyzed by NCI scientists, statistical staff, and international researchers. Analyses will include:

- Socio-demographic characteristics (e.g. age, sex, educational attainment, region of residence) of the sample with a comparison of this population to the US population to examine the extent of representativeness, as well as a comparison to the samples from other participating countries.
- Responses to the survey questions, specifically describing proportions, with 95% confidence intervals.
- Responses to each question by age group, sex, ethnic group, educational attainment and any other indicator of socioeconomic status.
- Proportions giving each response to each question. For the purposes of this analysis, dichotomized responses to the questions will be used.
- Association between levels of cancer awareness and beliefs and cancer outcomes, using data generated by Module 1 of the International Cancer Benchmarking Partnership (ICBP). For these questions, a plot of the age- and socioeconomic group standardized proportions giving each response against 1-year cancer survival (standardized for age, sex and cancer site distribution) and proportion with advanced

stage at diagnosis, to generate hypotheses about which might be most important in explaining cancer outcomes.

- Associations between knowledge of symptoms and anticipated delay, matching, to the extent possible, the disease assessed in the symptom knowledge to the symptom in the anticipated delay. These analyses will test the hypothesis that people will anticipate going seeking medical sooner if they associate a symptom with cancer.
- Rankings of cancer awareness and beliefs against rankings of cancer outcomes.

Findings from the ABC study will be disseminated through summary reports and data analysis presented at national conferences and published in peer-reviewed journals.

The project time schedule is as follows (see Table A.16-1):

Table A.16-1 Project Time Schedule

	Months after OMB approval							
	Months 1-3	Months 4-6	Months 7-9	Months 10-12	Months 13-18	Months 18-24	Months 25-31	Months 32-36+
Develop sample								
Train interviewers								
Implement survey								
Data processing/ quality checks								
Final SPSS dataset and tables								
Data analysis								
Publication								

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

The ABC study will not require exemption from displaying the expiration date of OMB approval. Any reproduction of the data collection instrument will prominently display the OMB approval number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The ABC study does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).