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MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES,
AND INDEPENDENT REGULATORY AGENCIES

FROM:

Cass R. Sunstein
Administrator

Handwritten signature of Cass R. Sunstein in black ink.

SUBJECT:

Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process

On January 21, 2009, the President issued a memorandum calling for the establishment of “a system of transparency, public participation, and collaboration.”¹ The memorandum required an Open Government Directive to be issued by the Director of the Office of Management and Budget (OMB), instructing “executive departments and agencies to take specific actions implementing the principles set forth in this memorandum.”

The OMB Director issued the Open Government Directive on December 8, 2009.² That Directive instructs the Administrator of the Office of Information and Regulatory Affairs (OIRA) to “review existing OMB policies, such as Paperwork Reduction Act guidance . . . to identify impediments to open government and to the use of new technologies and, where necessary, issue clarifying guidance and/or propose revisions to such policies, to promote greater openness in government.”³ In accordance with the Directive, OIRA has issued several guidance memoranda⁴ designed to promote open government and to assist agencies in complying with the Paperwork Reduction Act of 1995 (PRA).⁵

The PRA was designed, among other things, to “ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government” and to “improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government

¹ Memorandum of January 21, 2009, on “Transparency and Open Government,” available at http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment and at 74 F.R. 4685 (January 26, 2009).

² OMB Memorandum of December 8, 2009, M-10-06, available at http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf.

³ *Id.*

⁴ See Memorandum of April 7, 2010, on “Information Collection under the Paperwork Reduction Act”; Memorandum of April 7, 2010, on “Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act”; and Memorandum of May 28, 2010, on “Paperwork Reduction Act – Generic Clearances.” These memoranda are available at <http://www.whitehouse.gov/omb/open>.

⁵ See 44 U.S.C. §§ 3501-3521.

and society.”⁶ Federal agencies play a critical role in collecting and managing information in order to promote openness, increase program efficiency and effectiveness, reduce burdens on the public, and improve the integrity, quality, and utility of information to all users within and outside the government.⁷

Pursuant to the Open Government Directive, this Memorandum addresses the question of whether and how the PRA applies in the context of scientific research. Scientific research is essential to achieving a broad range of national goals, including improving public health, protecting national security, and increasing energy efficiency and environmental quality. Government-sponsored science plays an important role in developing solutions to our most pressing problems. This document explains how the PRA process can be streamlined and simplified in the context of such research. It should be seen as part of OIRA’s continuing efforts to work collaboratively with agencies to promote open government and to facilitate timely and efficient compliance with the PRA.

This Memorandum consists of three parts. First, it explains that the Paperwork Reduction Act does not apply to certain kinds of scientific research—specifically, collections that are neither “sponsored” nor “conducted” by the agency as well as those that are subject to what is commonly termed the “clinical exemption.” Second, it describes several possible options for streamlining the PRA process, including generic clearances and emergency review; some of these options may be available to agencies engaging in scientific research. Finally, it offers suggestions for strategies that agencies can use (such as early collaboration with OMB) to expedite the PRA process as a whole.

I. Cases in which the PRA does not apply

The PRA does not apply to some types of information collections of likely relevance and importance to scientific researchers.

A. Collections that are neither “sponsored” nor “conducted” by the agency

The PRA states that “an agency shall not conduct or sponsor the collection of information unless . . . [OMB] has approved the proposed collection of information.”⁸ When an agency is not conducting or sponsoring the information collection, the PRA does not apply. If, for example, a private organization is conducting research and collecting information, the PRA is inapplicable even if an agency is informed and provides suggestions, advice, and technical assistance (so long as the agency is not making a specific request or in a position to approve a collection or its design).

⁶ 44 U.S.C. § 3501.

⁷ 44 U.S.C. § 3506(b).

⁸ 44 U.S.C. §3507(a). The PRA defines agency as “any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.” 44 U.S.C. § 3502(1).

An agency “conducts” a collection of information if it collects the information itself, using its own staff and resources.⁹ An agency “sponsors” a collection if the agency (1) causes another agency to collect the information, (2) contracts or enters into a cooperative agreement with a person to collect the information, (3) requires a person to provide information to another person, or (4) in similar ways causes another agency, contractor, partner in a cooperative agreement, or person to obtain, solicit, or require the disclosure to third parties or the public of information by or for an agency.¹⁰

Information collections that are carried out by Federal grantees are subject to the PRA only if (1) the grant recipient is “conducting the collection of information at the specific request of the agency” or (2) the “terms and conditions of the grant require specific approval by the agency of the collection of information or collection procedures.”¹¹ If either of these conditions is met, then the grantee’s collection of information is subject to the PRA; the sponsoring agency must seek and obtain OMB approval for the collection, and the grantee must display the OMB control number on the collection instrument.

By contrast, collections of information that are conducted through Federally-funded, investigator-initiated grants¹² are generally not subject to OMB review under the PRA, as these grantee-conducted collections have not been specifically requested by the agency and do not require the agency’s specific approval. For example, the National Science Foundation (NSF) has many program areas that support investigator-initiated basic research on a wide variety of topics. Although NSF panels review the proposals, and although NSF funds the research, NSF does not specifically request the information collection or approve the collection or the collection procedures. As a result, such information collections are not subject to the PRA.

In the context of collections that are not Federally funded, a Federal agency does not “sponsor” an information collection if it merely provides suggestions, advice, or technical assistance to a non-Federal entity (governmental or private) that will conduct the collection on its own initiative. For instance, the Centers for Disease Control and Prevention (CDC) routinely provide technical assistance to State, local, tribal, and foreign governments in the development, by those governments, of surveys that those governments will undertake to characterize disease incidence or public health infrastructure readiness. The technical assistance that the CDC provides does not constitute “sponsorship” under the PRA, and thus the PRA does not apply to those surveys.

When difficult questions arise, agencies are encouraged to discuss specific cases with their OMB desk officers prior to the collection of information to determine whether the collection is subject to the PRA.

⁹ 5 C.F.R. §1320.5(a); 5 C.F.R. §1320.3(d).

¹⁰ 5 C.F.R. §1320.3(d). The PRA defines a “collection of information” as the “obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency.” 44 U.S.C. § 3502(3)(A). *See also* 44 U.S.C. § 3502(13).

¹¹ 5 C.F.R. § 1320.3(d).

¹² In this context, the term “investigator-initiated grants” refers to Federal agency (e.g., the National Institutes of Health or the National Science Foundation) funding of non-Federal researchers to investigate a topic of their choosing using an appropriate method. The granting agency may identify the general area in which research funds are available, but the non-Federal researchers define the hypothesis to be tested and the method to be used to test it.

B. Clinical exemption

OMB regulations specify categories of items that are not considered “information” under the PRA.¹³ One such category is commonly termed the “clinical exemption.” This category includes “facts or opinions obtained initially or in follow-on requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens.”¹⁴

To identify the cases to which this exemption applies, agencies should determine whether facts and opinions will be solicited during a treatment or clinical examination, or as part of a follow-up collection related to the treatment or examination (such as during a clinical trial for a cancer treatment or a study conducted in the course of treating veterans’ medical symptoms). If so, the data collection is not subject to the PRA if the facts or opinions gathered will be “in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of a disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens.”

II. Procedural options under the PRA

When the PRA does apply, it requires the relevant Federal agency to seek public comment on the proposed collection and to submit it to OMB for review and approval. To obtain the public’s input on an agency’s proposal to collect information, the PRA directs agencies to publish a 60-day notice in the *Federal Register* soliciting public comment. The notice must include a specific request that the public evaluate whether the proposed collection of information is necessary; evaluate the accuracy of the agency’s estimate of the burden that the collection would impose on respondents; comment on how to enhance the quality, utility, and clarity of the information to be collected; and comment on how to minimize the burden of the collection of information.¹⁵

After conclusion of the 60-day comment period and the agency’s internal consideration of the public’s comments, the agency submits the proposed collection to OMB and publishes a second *Federal Register* notice to announce the start of OMB review.¹⁶ This second notice informs the public about how to submit comments to OMB and informs the public that OMB may act on the agency’s request only after the 30-day comment period has closed. Figure 1 outlines the clearance process.

¹³ 5 C.F.R. § 1320.3(h).

¹⁴ *Id.*

¹⁵ 44 U.S.C. § 3506(c)(2)(A).

¹⁶ 44 U.S.C. § 3507(a)(1)(D). If a new information collection is associated with a proposed rule, OMB regulations require only one notice to be published. Agencies include this PRA notice in the preamble to the proposed rule and comments are directed to OMB. *See* 44 U.S.C. § 3506(c)(2)(B); 5 C.F.R. §1320.11.

Figure 1: The PRA Clearance Process

In cooperation with Federal agencies, OMB has devised a number of options designed to streamline this process, and some of these options will be of particular interest to those conducting scientific research. In many cases, these options offer flexibility in the structure and timing of the public notice-and-comment period required by the PRA. To realize the full potential of these options, however, some agencies may need to streamline their internal processes to support more timely submission of information collection requests to OMB.

A. Generic clearance

The PRA’s implementing regulations define “collection of information” to include “plans” to collect information.¹⁷ OMB supports innovative strategies or “plans” for managing and reviewing collections of information more efficiently, as long as those strategies advance the objectives of the PRA.

A generic information collection request is a request for OMB approval of a plan for conducting more than one information collection using very similar methods when (1) the need for and the overall practical utility of the data collection can be evaluated in advance, as part of the review of the proposed plan, but (2) the agency cannot determine the details of the specific individual collections until a later time. Most generic clearances cover collections that are voluntary, low-burden (based on a consideration of total burden, total respondents, or burden per respondent), and do not raise significant substantive or policy issues. Importantly, a generic clearance may cover multiple Federal agencies, with one agency as the lead.

Generic clearances can be used for a number of information collections related to scientific research, including formative research studies and methodological tests. To obtain a generic clearance, agencies provide the public with opportunity for comment as required by the PRA and provide all information that would allow for meaningful comment, including a description of the need for the collection, the general nature of the collection, an estimate of the overall burden, and a description of the methodologies that will be used to collect the data. Once approval is granted for the overall collection, individual collections that fall within the generic clearance are reviewed on an expedited basis and are not generally required to undergo further

¹⁷ 5 C.F.R. § 1320.3(c)(1).

public comment. They may remain in place for up to the PRA’s maximum approval period of three years.¹⁸

There are many examples that bear on scientific research. Agencies that regularly do pre-testing and development work (e.g., cognitive interviews, focus groups, and respondent debriefings) for surveys have found it beneficial to obtain a generic clearance for these kinds of studies when they cannot predict the specific surveys or sections of a survey for which testing will be needed.¹⁹ A generic clearance can also facilitate iterative rounds of testing. For example, the Census Bureau received a generic clearance for a program of evaluations and experiments for the 2010 Decennial Census.²⁰ These experiments included tests of alternative question wording, different messages given to respondents about the due date of the survey and privacy, and different contact strategies for non-response follow-up. Other surveys were included to assess the reliability of responses through re-interviews, as well as levels of respondent satisfaction. Similarly, the NIH has a generic clearance for formative research associated with developing and testing protocols associated with the National Children’s Study.²¹

Agencies have also received generic clearances for the implementation of collections that use identical methodologies or otherwise share a common element upon which public comment can be meaningfully solicited in advance, even if the specifics of each collection cannot be determined until shortly before the data are to be collected. For example, the National Center for Education Statistics (NCES) has used a generic clearance for a Quick Response Information System²² that uses well-defined sampling frames and follows clearly prescribed survey methods to obtain timely information from state education agencies, school districts, schools, and postsecondary institutions. Similarly, the National Center for Health Statistics has a generic clearance for the State and Local Area Integrated Telephone Survey.²³ This generic clearance approves a sample design and frame, and allows submission of recurring instruments without additional comment periods. (Note, however, that new instruments or significant changes to the sampling frame may sometimes require a public comment period.)

OMB continues to work with agencies to explore other types of collections that would benefit from the use of generic clearances, including in the domain of scientific research. Such clearances could be an appropriate tool for agencies that engage in standardized but intermittent data collection triggered only under specified conditions that may occur in the future—for example, food poisoning epidemics, pandemics, hazardous waste accidents, or hurricanes, tropical storms, and floods. In these situations, the agency’s submission should include:

- its generalized plan for data collection in such situations;
- the goals of the collection;
- the key research questions that would need to be addressed;

¹⁸ See 44 U.S.C. § 3507(g).

¹⁹ See, e.g., The National Center for Health Statistics’ “Questionnaire Design Research Laboratory” (OMB # 0920-0222); NIH’s “Formative Research, Pretesting, and Customer Satisfaction . . .” (OMB # 0925-0046); and the NIH’s “Questionnaire Cognitive Interviewing and Pretesting” (OMB # 0925-0590).

²⁰ “Generic Clearance for 2010 Census Program for Evaluations & Experiments” (OMB # 0607-0952).

²¹ “National Children’s Study Formative Generic Clearance” ICR (OMB # 0925-0590)

²² “NCES Quick Response Information System” (OMB #1850-0733).

²³ “State and Local Area Integrated Telephone Survey (SLAITS)” (OMB #0920-0406).

- the protocols or standard operating procedures that would be used;
- sample instruments;
- a description of the target population subgroup (e.g., health care providers, critical infrastructure providers, educators); and
- the likely temporal and geographic scope of the project.

Once the overall package is approved in advance of the triggering event, the agency need only submit the specifics associated with the particular study deemed necessary in response to that event (such as the likely size of the population, likely time period over which data collection will occur, which of the sample instruments will be used and how they will be tailored to the situation). No additional public comment period for the specific study would be necessary. Such advance review and approval permits agencies to respond quickly to the need for data. The Food and Drug Administration, for example, has a generic clearance for rapid response surveys designed to collect hazard analysis and/or risk management safety data on medical product impacts, which would be triggered by an adverse event potentially associated with a medical product.²⁴

Agencies are encouraged to consult with their OMB desk officers before developing a generic clearance to determine if it is appropriate, and if so, how it might be structured. OMB has also issued guidance that addresses frequently asked questions about generic clearances.²⁵

B. Emergency review

Under certain circumstances, an agency head or designee may request that it be permitted to seek expedited, or “emergency,” OMB review of an information collection request. The statute and implementing regulations give OMB the authority to grant expedited review if “(i) public harm is reasonably likely to result if normal clearance procedures are followed; (ii) an unanticipated event has occurred; or (iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.”²⁶ Emergency review approval depends on a number of factors including, but not limited to, the imminence and likelihood of the stated public harm; the unforeseeability of the event or statutory or court-ordered deadline; and the necessity of the information collection to the mission of the agency.

For example, public harm would be reasonably likely to be prevented through an emergency collection if an agency’s response strategy depends on a survey arising out of a public health epidemic. Unanticipated events could include a natural disaster, serious accident, or economic crisis that gives rise to a need to provide benefits quickly to the victims dependent on collected data. Along similar lines, normal clearance procedures may be reasonably likely to cause a statutory or court-ordered deadline to be missed if, say, a new statute is passed that requires implementation of an information collection within 60 days (which clearly is shorter than the PRA timeframe).

²⁴ “Generic FDA Rapid Response Surveys” (OMB # 0910-0500).

²⁵ Memorandum of May 28, 2010 on “Paperwork Reduction Act – Generic Clearances,” available at http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf.

²⁶ 44 U.S.C. § 3507(j)(1); 5 C.F.R. § 1320.13(a).

To request expedited processing, an agency head or designee must provide a written determination specifying which of the above circumstances merit consideration for emergency clearance.²⁷ Moreover, the agency must take all practicable steps to consult with members of the public, although OMB may modify or, if necessary, waive the public comment requirements.²⁸ (For instance, OMB waived the public comment period for collections that were associated with the immediate response to the 9/11 attacks and Hurricane Katrina.) Once emergency clearance has been approved, such approval and the associated control numbers are not valid for more than 180 days from the date that the agency requested approval.²⁹ After that date, the agency must apply for PRA clearance under the statute's normal procedures.

III. Managing the PRA timeline

Agencies can work with researchers and OMB to streamline the preparation and review of an information collection request through several strategies and sound advance planning.

A. Early collaboration

Early consultation with OMB prior to the submission of an information collection request can greatly facilitate review and decrease the potential for delay. Such early consultation can be especially valuable when an agency is planning a large survey, a policy-relevant data collection system, a major revision to an ongoing survey, or a large-scale methodological test. In this less formal context, OMB can advise on potential areas of concern, including the practical utility of the study, the survey methodology, and the statistical sample design.

Pre-submission consultation can also conserve valuable resources when an agency is undertaking complex, multi-phased collections of information—for example, when an agency is seeking approval for field testing or pilot experiments designed to inform larger studies. OIRA staff can provide advice on structuring the requests in such a way as to facilitate OMB review as the project moves through its various phases. If this pre-submission consultation takes place concurrently with the statutorily required 60-day notice-and-comment period the overall time that the package is under review at OMB can be significantly shortened.

B. The agency's request for OMB approval

The PRA requires the agency to demonstrate the practical utility of the collection and to explain how the agency will use the information.³⁰ In preparing its submission (including its supporting statement) to OMB,³¹ the agency should provide a careful discussion of what will be

²⁷ 5 C.F.R. § 1320.13(a).

²⁸ 5 C.F.R. § 1320.13(c) and (d).

²⁹ 44 U.S.C. § 3507(j)(2).

³⁰ 44 U.S.C. §§ 3501, 3508.

³¹ The application for clearance under the PRA is termed the “supporting statement.” See OMB Form 83-I, Paperwork Reduction Act Submission, Supporting Statement: <http://www.whitehouse.gov/sites/default/files/omb/inforeg/83i-fill.pdf>.

achieved by collecting the information and the quality of information that will be obtained using the proposed design.

In the context of scientific research, the agency should explain how the collection would fill gaps in current knowledge and include a brief review of existing information and the relevant scientific literature. The agency should provide sufficient background information to explain the need for the collection and how the study will meet that need. If the information is a continuation of a prior collection, the request should document how the information has been used and the continuing need for the collection.

The request should also contain an appropriately detailed description of research objectives and how the collected information will be used. Some scientific research is conducted primarily to shed light on causal relationships. Many public health data collections are designed to assess current conditions and inform appropriate responses to them (as in the case of an epidemic), assess local needs, inform decisions about program design and funding, and create baseline data against which future data will be analyzed. If the information being collected will likely inform policies, it is important to discuss the connection between the design and the use of the data.

Relevant OMB guidance can be found in the OIRA memorandum of January 20, 2006, on “Guidance on Agency Survey and Statistical Information Collections.”³²

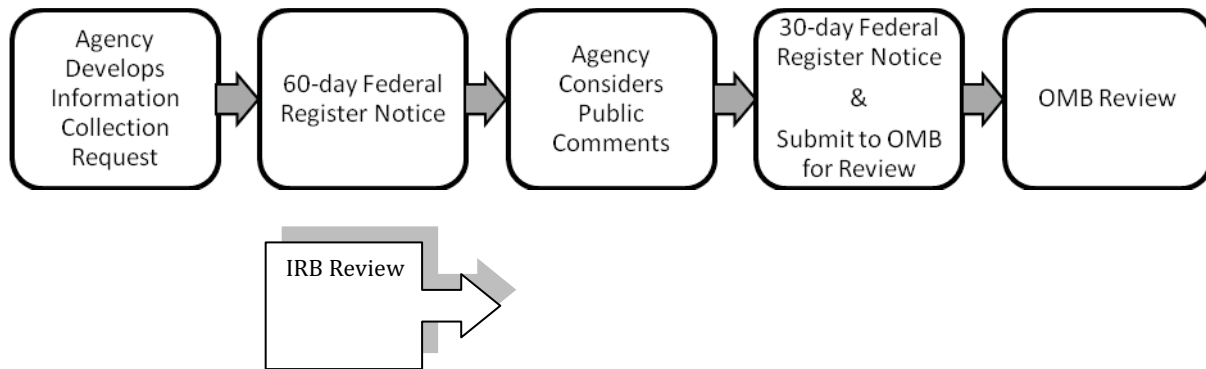
C. Simplifying overlapping processes

Some information collections are subject to additional statutory, regulatory, or internal programmatic policies that also require an evaluation of the study design, protocols, and collection instruments. In collaboration with OMB, agencies are encouraged to streamline processes, and to avoid unnecessary delay and duplication, by asking whether compliance with these additional requirements might also help meet the requirements of the PRA.

OMB recommends that agencies publish their 60-day Federal Register notice soliciting public comment concurrently with these other review processes. For example, research that is subject to the Common rule³³ is evaluated by an Institutional Review Board (IRB), a formally designated committee for approving research involving human subjects. Agencies need not wait for approval by the IRB to submit their 60-day notice, as the protocol and instruments submitted for IRB review constitute much of what is needed to request meaningful notice-and-comment from the public during the initial 60-day period.

³² The memorandum is available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/pmc_survey_guidance_2006.pdf.

³³ The Common rule (codified by Department of Health and Human Services at Subpart A of Title 45 C.F.R. Part 46 and adopted by 15 U.S. Federal departments and agencies) describes when approval by Institutional Review Boards (IRBs) is necessary.

Figure 2: Concurrent Notice Publication

More specifically, the agency can proceed with a 60-day notice once it can provide the public and stakeholders with enough information to allow them to assess whether the proposed collection of information is necessary; evaluate the accuracy of the agency's estimate of the burden that the collection would impose; comment on how to enhance the quality, utility, and clarity of the information to be collected; and comment on how to minimize the burden of the collection.

When researchers have developed a statement of purpose, study design, protocol, and data collection instruments, they have sufficient information to estimate the burden of the survey, and thus sufficient information to publish the PRA-required notice and comment. Agencies may use other mechanisms for consulting with the public (for example, peer review or small business advocacy review panels) that similarly yield the information necessary to publish the 60-day notice.

D. Minimizing duplicative work

Much of the information required for approval under the PRA is often available or has already been created by the researchers, perhaps in different formats, for other uses. For example, the documentation that researchers typically submit to their IRBs, or for agency approval of the research project, often overlaps with the information necessary for review under the PRA. Similarly, statements of work or research design plans prepared by agency research staff or research contractors often contain the requested information, sometimes in greater detail.

To streamline the review process, OMB has been developing, on a trial basis, ways to minimize duplicative work in preparing materials for OMB by having researchers submit their existing protocols, statements of work, or other similar documentation in lieu of parts of the supporting statement. Even if the purpose of the documents prepared for IRB review or contract review is not the same as the purpose of the request for OMB approval, agencies may consider submitting those documents as substitutes for parts of the supporting statement if the information sought by OMB is available in these documents.

Specifically, for information collections that include a survey or a census, or that use statistical methods, OMB requires information about sample and research design, data collection methods, statistical methods for estimation and analysis, and any pretesting results to be submitted as part of the request. This section of the request is referred to as “Part B” of the supporting statement. To the extent that the agency has other documentation that provides a detailed description of the study design and implementation plans, that documentation may be submitted in place of Part B, provided that it includes descriptions of the target population, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. If any of these items is not discussed and justified in the existing document(s), the agency may submit this additional information to OMB.

OMB is implementing this option on a trial basis to see if it proves helpful for agencies and streamlines OMB review. Agencies interested in this approach are encouraged to discuss with their OMB desk officers what documentation their researchers routinely prepare and how this information can best be used for multiple purposes. General OMB guidance on when Part B of the supporting statement is required, as well as more general guidance about using effective and efficient survey and statistical methodologies, can be found in the previously-referenced “Guidance on Agency Survey and Statistical Information Collections.”³⁴

³⁴ See supra note 32.