

When Less Paperwork Means No Science

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The Paperwork Reduction Act of 1995 has had the unintended effect of impeding research and evaluation in public health. The Centers for Disease Control and Prevention regularly conduct public health studies that go through standard scientific review processes, but PRA rules add an unnecessary layer of bureaucracy, requiring review by the Office of Management and Budget. The additional review is superfluous and can add months or years to the project, delaying the collection of critical data and violating core ethical principles for the just provision of the health services. As Congress prepares to reauthorize the PRA, the time is ripe to consider its original purpose, to examine how its implementation has impaired public health research in the past decade, and to consider alternative policies to reduce administrative costs and streamline data collection for public health purposes. Exemptions from OMB review already exist for federally funded clinical research programs, and Congress can solve these problems for the CDC by adding an exemption for public health research that involves voluntary data collection from citizens.

This problem needs to be addressed as soon as possible. The time is right: there is a great need to reduce or eliminate unnecessary government programs where possible, and the Obama administration has signaled its intention to place a new premium on using science to leverage investment in public programs.

The PRA and scientific research

Congress revised the PRA in 1995 and a broad bipartisan group supported its quest to reduce the burden to citizens associated with government data collections. The legislation has been overdue for reauthorization since 2001. As commonly understood by many Americans, the impetus for this law stemmed from mandatory reporting requirements like those imposed by the U.S. Census and tax forms. It was also intended to reduce the burden of repeated requests for the similar information required as a condition for receipt of services or benefits (e.g., federally funded insurance programs) or reporting from such programs. However, the language of the PRA was sufficiently broad to encompass federally sponsored public health data collections in which participation is voluntary and often compensated—for example, voluntary behavioral surveys, and projects that collect behavioral risk data collected in conjunction with the offering of disease screenings must be reviewed and approved by OMB before enrollment can begin.

For data collections by government agencies such as the CDC, the OMB administrative review process should require six to eight months after all human subjects reviews have been completed. In our experience, these timelines are minimum estimates, and many OMB reviews of public health research data collection protocols have taken much longer, often more than a year, and sometimes as long as three years. This results in delayed implementation of important public health data collections and forces public health decision makers to plan and implement programs without the benefit of timely and relevant data.

Ethical considerations

In considering PRA requirements in the context of public health research, policymakers must consider the principles espoused in the Belmont Report—the landmark statement on bioethics in human subjects research—which include respect for persons, beneficence, and justice. Unfortunately, delays in PRA reviews violate all three principles. With regard to respect for persons, delaying the opportunity of individuals to choose to participate voluntarily in a public health research study is not consistent with respect for the autonomy of persons to choose for themselves. With regard to beneficence—making efforts to secure the well-being of persons—if the OMB review process results in the delayed opportunity for voluntary research participation by those in greatest need (and in our experience it does), this clearly compromises the principle of beneficence. Unnecessarily long reviews also compromise the principle of justice by delaying access to voluntary participation in research studies. According to the Belmont report, “an injustice occurs when some benefit to which a person is entitled is denied without good reason.” This is especially evident in light of the fact that individuals choosing to participate in public health research studies may create direct and immediate benefits for themselves and those in their own communities by increasing knowledge about the impact of public health programs and by providing data to inform development of policies and improved programs.

The purpose and reality of PRA requirements

The stated purposes of the PRA include minimizing the burden of data collections on individuals, ensuring the greatest possible benefit from information collected, and reducing the cost to the federal government of collecting information. The principles are important, but the nature of CDC public health research fulfills them without additional review requirements. Moreover, OMB review can reduce the benefits of information gathering by duplicating existing review processes and delaying access to new health data. Here we address these purposes in turn as they relate to public health research and evaluation:

Minimizing the burden of data collections on individuals: Most citizens will identify the PRA with data collections that are *mandatory and involuntary*—for example, tax, census, and immigration forms. In fact, the PRA itself defines data collection as occurring when data collection “requirements [are] imposed on ten or more persons.” However, OMB review requirements have been increasingly applied to CDC public health research programs in which participation is voluntary, and even for which participants are monetarily compensated for their time and effort. The OMB review process has been extended to cover activities which do not impose a burden on citizens, but instead offer them the choice to participate in research that is designed to promote the health of communities in which they may receive services not yet widely available, and for which their time is compensated. In other words, burden does not result when people are offered a choice as to whether they want to participate in a public health research or evaluation study and the choice does not affect any services they already have available. Therefore, requiring PRA oversight of such studies beyond peer review and Institutional Review Board examination does not reduce the burden to participants.

Implicit in this purpose is that reducing duplicative data collections supported by the federal government would reduce unnecessary burden. However, there are many other funding mechanisms, such as National Institutes of Health grants, for which OMB does not provide oversight of most data collections because of a “clinical exemption” in the PRA, or because funding mechanisms are used in which government scientists do not have substantial input or direction with respect to data collections. In these cases, truly duplicative data collections are relatively rare. This is because scientists take seriously our responsibility to be well-versed in the published literature, to keep abreast of other ongoing research through networking with colleagues, and to not conduct research that unnecessarily duplicates other ongoing efforts. NIH review processes also help identify potentially overlapping areas of investigation in the peer review process. CDC, which is increasingly using peer review processes consistent with those of NIH, should similarly rely on the integrity of scientists and the diligence of peer review committees to address concerns of duplicative research.

Ensuring the greatest possible benefit from information collected: To provide maximal benefit, public health data collections, whether research or part of non-research public health surveillance or evaluation efforts, must be timely. The greatest possible benefits of data collection are to have the right data at the right moment. There are a number of processes already in place to ensure that public health research studies are collecting the right data. Research proposals are peer reviewed by external experts, and, in the case of research cooperative agreements, have substantial input from CDC scientists. In our experience, the OMB review process is in part duplicative of the peer review process. For example in a recent OMB review of one of our studies, there were no questions about the burden of our study; in fact, the only questions raised dealt with sampling methods and other aspects of scientific study design that peer reviewers had already examined and found meritorious. In our case, this issue was exacerbated by the fact that the original study proposal to CDC, which detailed the sampling methods and rationale, was not even reviewed by OMB staff as part of their review process.

Timeliness of data collection also relates in important ways to maximizing benefits. The OMB process unequivocally delays the collection of crucial public health data—sometimes by years. But even the lost benefit of science delayed only tells part of the story: CDC scientists, daunted by the realities of how long OMB approval sometimes takes, may self-censor their best ideas about public health science because they understand that by the time required OMB processes are completed, the science will be out of date. Increasingly, academic and other non-federal scientists are choosing to limit their collaborations with CDC because of OMB delays, in favor of working with other funding agencies where OMB review is usually not required.

Minimize the cost to the federal government of information collected: There might be instances in which OMB review identifies duplicative data collections, and costs are reduced because OMB intervention prevents such redundancy. However, we believe that much more frequently, costs increase because review delays necessary, well-coordinated data collections. When CDC has funded scientists in partner institutions to conduct important public health research and those researchers sit idle waiting for OMB approval, dollars are wasted. When important science is not done in a timely manner, we can measure the costs of failing to implement effective prevention programs both in dollars, because in many situations preventing disease costs less than treating it, and in preventable morbidity and mortality.

A case study

We base our observations of the OMB process on our recent experience. A group from the University of Maryland and the University of Pennsylvania were awarded funds under a cooperative agreement with scientists from the CDC to conduct a project in Philadelphia and Baltimore to examine the impact of conducting rapid HIV testing in inpatient and outpatient mental health settings that predominantly serve African Americans. This cooperative agreement was funded to 1) increase the number of mental health providers who routinely provide HIV counseling, testing, and linkage to care in settings that provide mental health care; and 2) to describe the relationship between mental illness and HIV testing and care for persons with newly diagnosed HIV infection and risk behaviors in order to inform optimization of HIV prevention interventions for persons with chronic mental illness. The proposal went through peer review, was approved, and funded beginning in August 31, 2007. More than two years later, we have not started work on the project and continue to await OMB approval. These delays represent a combination of internal CDC processes in preparing and submitting the OMB package and in OMB review of the data collection. Whether the OMB-related delays reside within CDC, elsewhere within the Department of Health and Human Services, or within OMB itself, these delays arise because of the OMB review requirements.

A simple solution

These concerns can be easily addressed in the next reauthorization of the PRA by providing an exemption to the PRA for public health research, surveillance, and evaluation in which participation is voluntary. Exemptions to OMB review are not without precedent. Notably, the NIH and the Veterans Administration, both of which have substantial intramural and extramural research programs, frequently use an exemption for clinical research. The legislation authorizing the National Vaccine Program also specifically exempts this program from the requirements of OMB review under the PRA. Public health research deserves no less.

The threshold to justify implementation of lengthy governmental reviews that delay scientific progress should be very high. In the case of the OMB review requirements for voluntary data collections for public health research and program evaluation, we believe that this threshold is not met. Although put into place to make sure that the American public is not overly burdened by government data collections, the OMB review process is currently applied to voluntary participation in public health studies that do not mandate participation, and therefore cannot mandate burden in its commonly understood sense. Because the OMB functions as part of the executive branch, the review process could be used as a political tool to modify or delay research that is unpopular within a given administration. This review process costs the public in many ways—counted in dollars as well as in delays of important research in public health that could ultimately save lives. Alternatives exist to meet the goals of the PRA for public health research that minimize delays in study implementation.

We are hopeful that Congress will take aggressive steps to review these policies and ultimately extend to these specific types of public health data collections an exemption from PRA requirements.

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