

SUPPORTING STATEMENT A

For

Assessing an Online Process to Study the Prevalence of Drugged Driving in the U.S.: *Development of the Drugged Driving Reporting System*

**National Institute on Drug Abuse (NIDA)
National Institutes of Health
Department of Health and Human Services**

August 25, 2015

Marsha F. Lopez, Ph.D., M.H.S
Chief, Epidemiology Research Branch
Division of Epidemiology, Services, and Prevention Research
National Institute on Drug Abuse (NIDA)
National Institutes of Health
6001 Executive Boulevard, Rm. 5144, MSC 9589
Bethesda, Maryland 20892-9589
Phone: (301) 402-1846
lopezmar@nida.nih.gov

Table of Contents

A.1 CIRCUMSTANCES Making the Collection of Information Necessary.....	4
A.2 PURPOSE and Use of the Information Collection.....	9
A.3 USE of Information Technology and Burden Reduction.....	10
A.4 EFFORTS to Identify Duplication and Use of Similar Information.....	11
A.5 IMPACT on Small Businesses or Other Small Entities.....	14
A.6 CONSEQUENCES of Collecting the Information Less Frequently.....	15
A.7 SPECIAL Circumstances Relating to the Guidelines of 5 CFR 1320.....	15
A.8 COMMENTS in Response to the Federal Register Notice and Efforts to Consult Outside Agency...	15
A.9 EXPLANATION of Any Payment of Gift to Respondents.....	15
A.10 ASSURANCE of Confidentiality Provided to Respondents.....	17
A.11 JUSTIFICATION for Sensitive Questions.....	18
A.12 ESTIMATES of Hour Burden Including Annualized Hourly Costs.....	19
A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers.....	20
A.14 Annualized Cost to the Federal Government.....	20
A.15 EXPLANATION for Program Changes or Adjustments.....	20
A.16 PLANS for Tabulation and Publication and Project Time Schedule.....	21
A.17 REASON(s) Display of OMB Expiration Date is Inappropriate.....	21
A.18 EXCEPTIONS to Certification for Paperwork Reduction Act Submissions.....	21

LIST OF ATTACHMENTS

- A. Drugged Driving Survey (DDS) instrument (Word version)
- B. Drugged Driving Survey (DDS) instrument (Screen shots of online version with \$0 incentive)
- C. Drugged Driving Survey (DDS) instrument (Screen shots of online version with \$10 incentive)
- D. Drugged Driving Survey (DDS) instrument (Screen shots of online version with \$20 incentive)
- E. Expert Panel Members
- F. Large Format Recruitment Materials
- G. Small Format Recruitment Materials
- H. IRB Approval Letter

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

The National Institute on Drug Abuse (NIDA) is requesting approval from the Office of Management and Budget (OMB) for data collection activities under U.S. Code Title 42, Chapter 6A, Subchapter III, Part C, Subpart 15, which states in part:

“(a) Authority - The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse.”¹

Background

Drugged driving is a serious problem in the U.S. A study of fatal crashes in 2009 showed that 18 percent of all fatally-injured drivers tested positive for drugs other than alcohol.² According to a recent study of six states that perform toxicological testing on drivers involved in fatal crashes, almost 40% tested positive for alcohol and almost 25% tested positive for other drugs. The study shows that the prevalence of other drugs increased from 16.6% in 1999 to 28.3% in 2010.³ In addition another recent study shows that drivers who tested positive for drugs have triple the risk of a fatal crash.⁴

The Office of National Drug Control Policy’s (ONDCP) 2010 National Drug Control Strategy identified drugged driving as a significant problem and established a goal of reducing U.S. drugged driving by 10 percent by 2015.⁵ This was the first time that ONDCP’s strategy identified drugged driving as a priority, and one that it continued in its 2011 strategy.⁶ The strategy aims to make the prevention of drugged driving on par with that employed to prevent drunk driving.

¹ Materials on NIDA’s Legislative Authority retrieved from <http://www.law.cornell.edu/uscode/text/42/285o-2>

² National Highway Traffic Safety Administration. (2010). Drug involvement of fatally injured drivers. Traffic Safety Facts Crash Stats (DOT HS 811 415). Washington, DC: National Center for Statistics and Analysis. Retrieved from <http://www-nrd.nhtsa.dot.gov/Pubs/811415.pdf>

³ Brady, J. E., & Li, G. (2014). Trends in alcohol and other drugs detected in fatally injured drivers in the United States, 1999-2010. *American Journal of Epidemiology*. Retrieved from <http://aje.oxfordjournals.org/content/179/6/692>

⁴ Ibid.

⁵ Office of National Drug Control Policy. (2010). National Drug Control Strategy, 2010. retrieved from <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf>

⁶ DuPont, R. (2011). *Drugged Driving Research: A White Paper*. Rockville, MD: Institute of Behavior and Health, Inc. Retrieved from http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/drugged-driving/nida_dd_paper.pdf

Despite those compelling data, in recent years many government and academic researchers have come to believe that the U.S. has not conducted enough research on the problem of drugged driving and a precise estimate of drugged driving prevalence is difficult to capture with the current disparate national and state-level data definitions, data capture tools, and data management systems.⁷ What is needed is a comprehensive understanding of the relationship between drugs and driving, along with the resulting arrests, accidents and fatalities that may be caused by driving under the influence of drugs.

Why NIDA is involved in drugged driving research

The National Institute on Drug Abuse (NIDA) joined with other Federal agencies to focus on this problem and issued a challenge to researchers through a Small Business Innovation Research (SBIR) request for response (RFR) (N43DA-12-5571- SBIR Phase I - Topic 146) to address the obstacle of gathering data to more clearly understand the problem of drugged driving. The RFR issued in November 2011 the U.S. Department of Health And Human Services requested that small business address future research directions in drugged driving.⁸ The RFR noted the following:

“...Several studies in the United States and European countries found that at least 35% of people stopped for erratic driving, drivers involved in a crash, and fatally injured drivers had at least one drug in their system, and many were under the influence of both drugs and alcohol. Marijuana is the most prevalent drug, after alcohol, found in samples from drivers involved in traffic accidents or stopped for impaired driving. Those and other released data have alerted the research community of the problem’s magnitude and the urgency of addressing it.

Major effort to address the drugged driving problem will have a significant effect on the demand for drugs and on drug use in the United States. However, this effort is being impeded by multiple factors: 1) lack of available or quality data to adequately understand the magnitude of the problem and its possible solutions; 2a) lack of prevention strategies specifically tailored to drugged driving; 2b) lack of understanding of ways to tailor existing effective strategies to address drugged driving; 3) lack of treatment interventions to address

⁷ DuPont, R. (2011). *Drugged Driving Research: A White Paper*. Rockville, MD: Institute of Behavior and Health, Inc. Retrieved from http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/drugged-driving/nida_dd_paper.pdf

⁸ National Institutes of Health and the Center for Disease Control and Prevention. (2011). Solicitation of the National Institutes of Health and the Centers for Disease Control and Prevention, for Small Business Innovation Research Contract Proposals. N43DA-12-5571- SBIR Phase I - Topic 146. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-108.html>

the problem, other than from a criminal justice perspective: 4) lack of effective policy approaches to address the patterns of drugged driving problems.”⁹

Advocates for Human Potential, Inc. (AHP) and Carnevale Associates, LLC (Carnevale) received a Phase I and Phase II SBIR contract from NIDA to develop the National Drugged Driving Reporting System (DDRS) which included the creation of a national minimum data set (NMDS) for drugged driving. During both phases the contracting team (AHP/Carnevale) worked with nationally-recognized expert panel members to develop a product that would meet the government’s need for data to better understand the magnitude of the problem as well as to identify possible public health prevention strategies.

As a result of the Phase I and Phase II expert panel meetings, the team decided to take a public health approach to collect self-reported driving behaviors through an anonymous online survey. This Information Collection Request (ICR) is for the implementation of a field test of the data collection process using an anonymous online survey in three states. While the survey will provide some additional data on drugged driving that may be useful in understanding the problem, the focus of the proposed study is to assess the following: (a) the process of conducting participant recruitment at state departments of motor vehicles with three different incentive amounts; (b) the use of an anonymous online survey; and (c), the effectiveness of that survey in collecting data elements for the NMDS.

After the field test is implemented and the process is assessed in three states, Phase II of the federally-funded SBIR will end. During the next phase of the project (Phase III), which will not have federal funding or oversight, the research team plans to implement the survey in as many states as possible to obtain a much larger sample that includes broader geographical coverage. These data from the larger sample will be used to increase understanding of the overall prevalence of drugged driving and the drivers who use medications and drugs while driving in order to develop prevention, detection and treatment strategies.

Historical Background

Over the past 40 years, public awareness of the dangers of ***drunk*** driving have dramatically increased, and there is commonly held public perception that alcohol impairs driving and can result in serious or fatal accidents. There is nationwide consensus on Blood Alcohol Concentration (BAC) impairment levels of impairment and this agreement, along with public awareness, have led to stricter laws and increased arrests and convictions.¹⁰ Plentiful drunk driving research provides detailed information about demographics, time of day, and type of crash related to drunk driving, which is used by law enforcement, prevention and treatment.

⁹ *ibid.*

¹⁰ All states define driving with a blood alcohol concentration (BAC) at or above 0.08 percent as a crime, but specific laws and penalties vary substantially from state to state. Retrieved from http://www.ghsa.org/html/stateinfo/laws/impaired_laws.html

What constitutes impairment?

Drugged driving is significantly different from drunk driving in terms of understanding what constitutes impairment. Toxicology testing for drugs is costly and time consuming and there is no agreement on what constitutes impairment with medications or drugs equivalent to Blood Alcohol Concentration (BAC). Because drugged driving is so difficult and costly to detect, it also differs significantly from drunk driving in terms of enforcement and prosecution.¹¹

Further, the prosecution of drugged driving is very challenging and time consuming because there is not a recognized agreement on what constitutes impairment. Individuals metabolize drugs differently. What may be one person's threshold for a drug may be different than another, making it impossible to set universal standards like the BAC level. As a result, 17 States developed *per se* laws to deal with drugs. These laws state that it is a crime to drive with any detectable amount of a drug or its metabolites in an individual's body regardless of whether a person is "impaired."

Drugs are difficult to detect

Drugged driving is significantly different from drunk driving in terms of detection. Because drugged driving is so difficult and costly to detect, it is also challenging in terms of enforcement and prosecution.¹² Biological testing for the presence of medications and drugs is not routinely done by law enforcement or prosecutors for a variety of reasons. Often drivers who are stopped by the police or who experience a car crash show obvious signs they have been drinking alcohol. Conducting a breathalyzer test is reliable and easy, and due to the acceptance of BAC levels, drunk driving is relatively easy to prove and prosecute. However, toxicology tests cannot be implemented in a roadside situation (and often require warrants for saliva, urine or blood samples), are expensive to conduct (\$200- \$300 or more per specimen). In addition a toxicologist must also testify at a trial, which has a cost in time and dollars. According to the former prosecutors and others on the expert panel, these are all the reasons law enforcement personnel will not often move to test for drugs unless a police officer suspects impairment and the driver's BAC is zero or low.

While helpful when implemented properly, *per se* drugged driving laws are clearly not a panacea, and the arrests and convictions under these laws do not reflect the true prevalence of drugged driving. A recent study that reviewed FARS data from States that have *per se* laws found no evidence that these laws reduce traffic fatalities.¹³ The study also revealed that *per se*

¹¹ Reisfield GM, Goldberger BA, Gold MS, DuPont RL (2012). The mirage of impairing drug concentration thresholds: a rationale for zero tolerance *per se* driving under the influence of drugs laws. *Journal of Analytical Toxicology*. 36(5), 353-6. Retrieved from <http://jat.oxfordjournals.org/content/36/5/353.abstract>

¹² Ibid

¹³ Anderson, MD, and Rees, DI, *Per Se Drugged Driving Laws and Traffic Fatalities*. IZA Discussion Paper No. 7048. Retrieved from <http://ssrn.com/abstract=2189786>

laws do not have any significant effect on traffic fatalities when considering age, gender, time of day, or day of the week.

Focused on enforcement

Thus far, the primary public policy response to the drugged driving problem has been to rely on enforcement. The National Highway Traffic Safety Administration (NHTSA) has made training more accessible to law enforcement in how to recognize cases of drugged driving through its Drug Recognition Expert (DRE) and Advanced Roadside Impaired Driving Enforcement (ARIDE) programs. These data from roadside detection programs provide important information about drugged driving, but the information is not necessarily representative of community-wide problem that could assist other interventions, such as prevention and treatment interventions, to prevent potential drugged driving.

Taking a public health approach

The Expert Panel convened for the Phase I SBIR confirmed what NIDA's RFR noted: Much of the policy development on drugged driving is driven from the drunk driving and criminal justice perspective. Panelists noted that currently there are not enough data about drugged driving to take a public health approach designed for this complex problem. The scant data that are available show such a wide range of people, places, medications and drugs, time of day and a myriad of other factors that render it impossible to impute findings from existing data.

In addition, panelists said that in order to target enforcement and policy, legislators and law enforcement all report that they need additional information about prevalence, specifically demographic information about who is driving under the influence of drugs, where and when it occurs, how often it occurs and which medications/drugs are being used. Data at the community, regional and statewide level is critical, especially for enforcement.

Panelists also expressed concern that the increasing number of States allowing medical marijuana, the legalization of marijuana in Colorado and Washington, and the decriminalization in other States significantly adds to the need for data involving drugged driving. Finally, they noted that any new data set emerging from this SBIR project needs to be comparable to existing data sets for effective research.

In addition, more knowledge is needed about prescription medication and illegal drug use as it relates to drugged driving, the prevalence of drugged driving and the reasons that drivers choose to drive while using a potentially impairing drug or combination of drugs. These data would better inform policy and program managers about how best to improve public health and safety.

While discussing the differences between taking an enforcement approach vs. a public health approach one Expert Panel member suggested that because of these previously mentioned barriers ***“we can't arrest our way out of this.”*** The Expert Panel felt that moving away from

focusing on more arrests and moving toward increased public awareness of the problem will result in better data to understand it. This is not to say that drugged driving should not be considered a legal problem at all; driving while impaired is dangerous and needs to be punishable by law, and more effective implementation of *per se* laws can be an important tool in the effort to reduce drugged driving. However, the ambiguities surrounding the drugged driving issue, including defining "impairment" in itself, make approaching drugged driving as *solely* a legal issue impossible and unsuccessful.

Past data collection efforts that are applicable to this study

The AHP/Carnevale team assessed existing survey instruments to assess whether data elements were already being collected by other federal agencies to eliminate as much overlap as possible. The team assessed instruments available from the Substance Abuse and Mental Health Services Administration (SAMHSA) And the National Traffic Highway Safety Administration (NHTSA). The limitations of these past data collection efforts are discussed in Section A.4.

A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION

The study seeks to provide an improved understanding of the prevalence of drugged driving among adult drivers in the U.S and will assess the effectiveness of the online survey implementation process. While the implementation of this survey will provide some additional data that may be useful in understanding the problem of drugged driving, the two primary purposes of the field test are to assess: (a) the implementation of a data collection process using an anonymous online survey in three states, and (b) whether the Drugged Driving Survey (DDS) is an effective instrument to collect the minimum data elements.

Once federal funding has ended, the plan for Phase III of the project will include a more distributed nationwide sample of states, and the individual response rates and state participation rates would be considered in developing and defining the sample used for a data collection process designed to provide comprehensive data on drugged driving.

The practical utility of information collected in Phase III will be to provide comprehensive, accurate and detailed data about drugged driving behavior useful to federal, state and local governmental agencies and non-governmental organizations in developing or improving programs to identify, prevent/reduce and treat problems related to drugged driving. As such, the field test of the Drugged Driving Survey during Phase II will collect self-reported information about a variety of demographic categories and driving behaviors.

Purpose of field test process data

In order to successfully complete Phase II, the data collection field test will be used to assess the usefulness of the National Minimum Data Set and the Drugged Driving Survey (DDS) and to evaluate the process used to recruit respondents. Although it will be a non-distributed sample, these data will contribute to a clearer picture of drugged driving in three states. Both of these

activities will influence possible changes to the NMDS, the DDS and the process for recruitment in Phase III of the project. The survey can be seen in Attachment A.

Phase III SBIRs do not receive government funding. One of the goals of the SBIR initiative is to develop a commercial product that will contribute to the overall greater good in addition to providing revenues to the contractor. In Phase III, without government funding, the AHP/Carnevale team proposes to construct and make available for public and commercial use the NMDS — and the survey that collects that information — by the following types of organizations and professionals:

- Researchers in the fields of transportation/highway safety, impaired driving, prevention and treatment of substance use disorders in federal and state agencies, as well as public/private academic settings and private for-profit programs (such as actuaries researching drugged driving for insurance companies.
- Public and private non-profit program planners/evaluators focused on highway safety, drugged driving prevention, detection and education programs at the national, state and local level.
- State, county and local law enforcement personnel and prosecutors.

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION

This project proposes to use an online survey system to make the survey easily accessible to a variety of potential respondents and to reduce the time/burden it may take. It also automates the data collection process which reduces the burden (time, effort and funding) to NIDA which is supporting this effort. The team’s preliminary assessment is that the online survey will take most respondents about 12 minutes, much less time than interviews or pen and paper responses. A number of research studies that assess web-based surveys show they are a useful medium to reach a broad range of people, are quick and convenient for those taking the survey and may reduce response bias in answering questions about potentially “sensitive” topics such as high risk behavior with using drugs and driving.^{14,15,16}

Respondents will enter data online using a survey created with software products already owned

¹⁴ Cantrell MA, Lupinacci P. (2007). Methodological issues in online data collection. *Journal of Advanced Nursing*. 60(5):544–549. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2648.2007.04448.x/abstract>

¹⁵ Hines DA, Douglas EM, Mahmood S. (2010). The Effects of Survey Administration on Disclosure Rates to Sensitive Items Among Men: A Comparison of an Internet Panel Sample with a RDD Telephone Sample. *Computers in Human Behavior*. 26(6):1327–1335. Retrieved from <http://dl.acm.org/citation.cfm?id=1853504>

¹⁶ Rhodes SD, Bowie DA, Hergenrather KC. (2003). Collecting behavioural data using the world wide web: considerations for researchers. *Journal of Epidemiological Community Health*. 57(1):68–73. Retrieved from <http://jech.bmj.com/content/57/1/68.abstract>

by AHP, such as Snap Survey Software or SurveyGizmo, to create the survey, and Microsoft Access, to house survey data.

Privacy Impact Assessment

A Privacy Impact Assessment (PIA) conducted and the form was submitted to the NIH Office of the Senior Official for Privacy (OSOP) on January 22, 2015. The subject of the PIA was an Electronic Information Collection. The form noted that the Drugged Driving Reporting System will not collect PII, is in the development phase of the Enterprise Performance Lifecycle, and is not a Federal Information Security Management Act (FISMA)-Reportable system. In addition, the NIH Security Authorization Tool (NSAT) Entity Creation form was also submitted for System/Third-party Website or Application (TPWA).

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

Why already available data cannot be used or modified

The initial idea for Phase I of the SBIR program was to knit together disparate drugged driving data systems into a single source of information to better inform attempts to control drugged driving. The Phase I team hypothesized that these data system linkages could provide evidence of national “hot spots” where drugged driving was most problematic so that public health and enforcement could come together to increase public health and safety. However, due to problems with database interoperability and confidentiality of data, it would be unlikely this approach would be successful. The AHP/Carnevale team also explored the idea of adding a few items to existing data systems, but learned after extensive study there would be significant limitations to adding questions to existing data collection efforts, and the data needed to assess the true threat to public health and safety caused by drugged driving could not be captured in a small number of items.

Findings from the review of the drugged driving literature and the extensive discussions with the Expert Panel confirmed that existing data systems available to policy makers and program managers are not adequate to explain the nature and extent of drugged driving and its consequences on public health and safety. The Expert Panel determined that there is currently no single data set that contains all, or even most variables that allow for sufficient and complete analyses to inform decision-making at any level of government. In the judgment of the AHP/Carnevale team, the proposed Drugged Driving Reporting System will fill that gap.

National Survey on Drug Use and Health

The primary and most widely available data set that presents a broader sense of drugged driving prevalence is from the Substance Abuse and Mental Health Services Administration’s (SAMHSA) National Survey on Drug Use and Health (NSDUH). In 2011, according to NSDUH, 9.4 million persons (3.7 percent) of the population aged 12 or older reported driving under the

influence of illicit drugs during the past year. While this represents a 12 percent decrease from the rate in 2010 (4.2 percent), it does not markedly lessen the threat that drugged driving poses to public health and safety. The NDSUDH does not include confirmation with biological samples; those surveys show a much higher rate of drugged driving. A recent roadside survey conducted in California — which combined a survey and confirmation with biological samples — indicated that more nighttime drivers tested positive for drugs (14.0%) than alcohol (7.3%).¹⁷ In that study 7.4% of the respondents tested positive for marijuana while illegal drugs and prescription and over-the-counter drugs each showed a 4.6% prevalence rate. Like the NSDUH annual survey, the study proposed in this OMB application will not use biological samples, but will use only self-reported data. However, the Drugged Driving survey will collect public health information from respondents that is not currently collected and which would be contributing factors for addressing the problem.

Fatality Analysis Reporting System

The National Highway Traffic Safety Administration's (NHTSA) Fatality Analysis Reporting System (FARS) does not include drug testing data for *all* drivers as it only monitors driver and passenger *fatalities*, which comprise only a small amount of total drugged driving incidents.¹⁸ FARS is a good source to measure the extent of drugged driving consequences, but fatal consequences are only a part of the overall issue. FARS' drug test variable includes whether or not the driver was tested for drugs, whether they tested positive for any drugs and if so which ones. FARS also notes the commercial license class of the driver. From 2005 to 2009, the percentage of drivers tested for drugs in FARS entries increased from 56 percent to 63 percent of all entries (15,363 to 13,801), while the proportion of all drivers in the system that tested positive for drugs rose from 13 percent to 18 percent (3,710 to 3,952) over that same period. However, when counting only the proportion of drivers who tested positive for drugs, those proportions increase from 28 percent to 33 percent from 2005 to 2009.¹⁹

National Automotive Sampling System

Likewise, the National Automotive Sampling System (NASS) is a representative sample of all automotive incidents with crashes, injury, or property damage in the United States. Further, while the NASS contains variables on drug use and the zip code of the driver, information on the type of license issued for the driver is not collected. In addition to improving safety (commercial

¹⁷ Lacey, JH, Kelley-Baker, T, Romano, E, Brainard, K, and Ramirez, A. *Results of the 2012 California Roadside Survey of Nighttime Weekend Drivers' Alcohol and Drug Use*. November 2012. Pacific Institute for Research and Evaluation Calverton, MD

¹⁸¹⁵ National Highway Traffic Safety Administration. (2010). Drug Involvement of Fatally Injured Drivers (DOT HS 811

415). Washington, D.C.: National Highway Traffic Safety Administration. Retrieved from <http://www.nrd.nhtsa.dot.gov/pubs/811415.pdf>

¹⁹ Ibid

vehicles are often larger and potentially more dangerous in a crash) more detailed information about drivers of commercial vehicles (e.g. age, zip code, details on driving behaviors) would be helpful to State regulators, employers and commercial insurers; these data will be included in the Drugged Driving Survey. However, this proposed project is not specifically targeting those with commercial driver's licenses (CDL) and it is unknown whether this convenience sample will include enough drivers with CDLs for statistical analysis.

National Roadside Survey National Roadside Survey

NHTSA conducts the National Roadside Survey (NRS) of Alcohol and Drug Use approximately every 10 years because the process of collecting oral and blood samples from a random selection of drivers is costly and time consuming. The survey began testing for potentially impairing drugs for the first time in 2007. However, because ONDCP has identified drugged driving as priority topic in the *National Drug Control Strategy*, NHTSA decided to conduct the NRS sooner in 2013; data will be available late 2014 or early 2015. While the NRS survey assesses driving behavior at one point in time confirmed by biological samples, it will not ask about past driving behaviors, near misses, and crashes that the Drugged Driving Survey will assess.

National Drive Register/Problem Driver Pointer System

Another resource for data is NHTSA's National Driver Register (NDR) and its Problem Driver Pointer System (PDPS). This data set contains information supplied by States as a result of convictions and license revocations/withdrawals pertaining to serious traffic violations such as driving while impaired by alcohol or drugs. Access to this information is limited to state and federal officials who are conducting investigations into individual accidents, and is therefore not useful to understanding drugged driving as public health issue.²⁰

Police Accident Reports

Another source for data is the Police Accident Reports (PARS). PARS data come from individual police department accident reports. They are very useful in providing details of a traffic event and even provide data for the FARS and NASS. However, PARS data are not standardized and vary by local jurisdiction in format and content.²¹ Because of this variance, access to data and the quality of data would vary, and the Expert Panel advised against it.

Prescription Drug Monitoring Programs

Finally, Prescription Drug Monitoring Programs (PDMPs) are State-based programs that assess the nature and extent of prescription drug abuse by collecting data on controlled substance prescriptions. Although not all PDMPs collect data on the same drugs, all PDMPs monitor some

²⁰ National Highway Traffic Safety Administration. National Driver Register. Retrieved from <http://www.nhtsa.gov/Data/National+Driver+Register>

²¹ National Highway Traffic Safety Administration. (2010). Drug Involvement of Fatally Injured Drivers (DOT HS 811 415). Washington, D.C.: National Highway Traffic Safety Administration. Retrieved from <http://www-nrd.nhtsa.dot.gov/pubs/811415.pdf>

set of controlled prescriptions, including patient information, prescriber information, dispenser information, drug information, and quantity and date dispensed. So far 34 States have operational PDMPs; 10 States and 1 Territory have enacted PDMP legislation and 6 States have legislation pending. As these systems are developed they will be greatly enhanced by the analytic potential of the National Drugged Driving Data System. For example, if a state PDMP learns through the drugged driving data that a particular demographic is driving while using prescription medications in one region of the state, the PDMP, state and local law enforcement can work together to target both the supply (e.g. overprescribing doctors) and the demand among individuals.

Conclusion

The most important innovation that the Drugged Driving Report System will introduce is a timely, comprehensive set of data to inform the public about the nature and extent of drugged driving. It will augment current data sets, such as FARS, so that the circumstances surrounding drugged driving become more well-known and understood. According to the most recently available National Drug Control Strategy from ONDCP, one of the recommendations is to "Collect further data on drugged driving."²² The NMDS is aligned with this recommendation, providing a practical and timely addition to what the National Strategy suggests.

There are a variety of potential uses for this enhanced knowledge base, particularly if it is ultimately expanded both regionally and nationally. First, policy and program managers at all levels of government will be better informed in developing and targeting prevention efforts, including dissemination of information to specific audiences such as the health community, patients, education facilities, and motor vehicle offices. Second, treatment providers may be better able to develop drugged driving education programs when they have a better understanding of the prevalence and nature of the problem in their area. Third, law enforcement will be supported in developing traffic safety plans and assignments of drug recognition experts (DRE) in specific geographic areas. Additionally, commercial vendors (e.g. insurance companies) might consider offering reduced rates to drivers who comply with requirements about using their medications and driving. These several examples demonstrate how the data collected by this survey can enhance existing information systems with respect to drugged driving in particular, and public health and safety more generally.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

No small businesses or other small entities will be involved in this study.

²² 2013 National Drug Control Strategy from Office of National Drug Control Strategy, p. 43.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

Participation in the survey is voluntary and information about it will be offered once to possible respondents within the time frame covered by this request.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.

This information collection fully complies with 5 CFR 1320.5(d)(2).

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY

The 60-day Federal Register Notice was published on November 24, 2014 (79 FR 69864 Page: 69864 -69865 (2 pages) Document Number: 2014-27760). There were no public comments received.

Expert Panel members including federal and non-governmental experts were consulted in Phase I of the project (August 2012 to February 2013) and in Phase II (starting in September 2013) in an effort to consult outside of the National Institute on Drug Abuse. A list of Expert Panel members can be found in Attachment E.

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS

Incentives

The AHP/Carnevale Team plans to market this survey and implementation process to other states and will analyze response rates obtained across the three different monetary incentive levels of the DDS. A study of incentive levels is necessary because the appropriate level of incentive cannot be determined in advance because this recruitment method (drivers at DMVs) has not been done before. In addition to a unique recruitment method, the survey asks potentially sensitive questions. Therefore, varying incentive levels will be used and analyzed to determine the lowest possible incentive rate that will yield the highest response rate. The analysis of response rates across incentive levels will provide valuable information about the costs of administering the survey to other states that may be interested in using the DDS in the future. This is being done because the federal SBIR program requires that contractors develop

commercially viable plans for selling the product after the contract ends. While there is ample literature available to show that incentives encourage participation in online research and evaluation studies generally^{23, 24, 25} it is not known how much of an incentive is required to motivate drivers to complete an online survey about drugged driving behaviors; the AHP/Carnevale team expects that the experience of recruiting a sample of 3,750 drivers across three states in a four-month period will provide additional data to determine an appropriate amount for future research.

First, the response rate of returned surveys will be analyzed as a proportion of the maximum number of possible returned surveys. For each level of incentive, the denominator used will be the number of recruitment “stickers” that will have been provided to the states initially. Within each level of incentive, the number of incomplete surveys and patterns of missing data within each incentive level will be analyzed, to inform understanding of response patterns. The counts of missing data across the survey as a whole will be analyzed, as well as within each section of the survey, to determine the degree of variability in patterns of responding, if any, across incentive levels.

Recruitment materials (see Attachments E and F) will be provided to the respective individual state Department of Motor Vehicles (DMV) to solicit survey respondents; the AHP/Carnevale Team will determine the appropriate number of materials to ensure a response by 1,250 drivers in each state. Within the initial set of recruitment materials provided to DMVs, 75% of the total number distributed will offer an incentive (50% of the materials will have a \$10 gift card incentive, while 25% will have a \$20 gift card incentive). The remaining 25% of the materials will not offer any incentive. (Screenshots of the DDS offering \$0, \$10 and \$20 incentives can be seen in Attachments B, C and D respectively.) The AHP/Carnevale team will work with DMVs to insure that DMVs provide recruitment materials to all drivers aged 18 and over during a given time period, estimated to be about four months. (Recruitment materials in both large and small formats can be seen in Attachments F and G.)

The materials will have a two or three character alphanumeric recruitment code (e.g. each \$20 gift card might have the code A2C) that the respondent will enter into the anonymous online survey. The recruitment code will only identify (1) the state in which the respondent visited the DMV, and (2) the level of incentive (none, \$10, or \$20). The code will not identify the respondent individually. When a respondent has completed the last question on the survey, the

²³ Sue, V. M., & Ritter, L. A. (2012). *Conducting online surveys*. Sage.

²⁴ Singer, E. (2011) Toward a Benefit-Cost Theory of Survey Participation: Evidence, Further Tests, and Implications. *Journal of Official Statistics*, Vol. 27, No. 2, pp. 379-392.

²⁵ Khadjesari, Z., Murray, E., Kalaitzaki, E., White, I. R., McCambridge, J., Thompson, S. G., Godfrey, C. (2011). Impact and Costs of Incentives to Reduce Attrition in Online Trials: Two Randomized Controlled Trials. *Journal of Medical Internet Research*, 13(1), e26.

survey software will generate a redemption code for the respondent, in the appropriate gift card amount (if any). The respondent will then use this redemption code at the National Gift Card Rewards (NGC) website to select their choice of gift (see detailed description below).

The AHP proposes to use a “QR code” (short for Quick Response Code) on recruitment materials. Potential respondents can scan the code using a QR scanner application on a smartphone or tablet and it will automatically bring them to the survey site, which is accessible using either a smartphone or a tablet. QR codes are frequently used in brochures, posters, product packaging and point-of-sale marketing to allow smartphone users immediate access to a web site for additional information. According to a 2012 market research study, 47% of consumers in the U.S. and Canada have used a mobile phone or other device to scan a QR code, and 83% of consumers are aware of these codes.²⁶

The AHP/Carnevale Team will contract with National Gift Card Rewards (NGC) for the gift cards. NGC offers a full range of card options, fulfillment services, and a secure redemption sites. The Team will get codes from NGC that can be given out as incentives and will allow the users to redeem the codes anonymously through a secure redemption site set up by the project team. Survey participants will have nearly 70 choices for redeeming their incentive at various retail online/brick and mortar stores and restaurants that will appeal to a wide range of drivers of all ages, genders and geographic location. Without providing these small incentives, participants may be less likely to participate in the survey. These incentives are only provided for individual respondents.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

No personally identifiable information (PII) will be collected in the survey. The survey notes the following on the first page:

“This survey is **completely anonymous** —*meaning no one will know your name or know where you were when you filled it out.* You will be asked some information about yourself such as age, gender, and zip code, but you will not be asked your name or any other personally identifying information.”

In addition the survey reminds respondents at the start of every new section that it is completely anonymous and private to the extent permitted by law; this information is repeated 20 times. In addition to not collecting PII, the web site housing the survey will not store IP addresses that

²⁶ Information from the BrandSpark / *Better Homes and Gardens* American Shopper Study retrieved March 31, 2014 from: http://bestnewproductawards.biz/usa/shopper_study.html

could be used to track respondents' location via an IP address to further ensure privacy to the extent permitted by law.

This Project is Not Subject to the Privacy Act

In addition to the fact that PII will not be collected, this data and the process to collect it is not subject to the Privacy Act because the Privacy Act binds only Federal agencies, and covers only records in the possession and control of Federal agencies. While this project is sponsored by NIH/NIDA, the SBIR program allows for small businesses (such as the contractors in this case, Advocates for Human Potential, Inc. and Carnevale Associates, LLC) to own the data collected through this process. However, a Privacy Impact Assessment was conducted (see page 11).

Review by an authorized Institutional Review Board as per 45 CFR 46 (Regulations for Protection of Human Subjects)

The AHP authorized Institutional Review Board (IRB) reviewed an IRB application and approved it through an expedited review under Federal-wide Assurance # 6316. (The IRB Approval Letter is included as Attachment H as part of this application.) An expedited review may be used for research which involves only procedures that involve no more than minimal risk. This review process may also be used to review minor changes in previously approved research during the period for which the approval is valid, and research which falls within the several exempt categories. One of the exempt categories is: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.)

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

As noted earlier in Sections A.1 and A.2, the problem of drugged driving is a serious problem in the U.S. The survey includes questions of a sensitive nature, such as drug and alcohol use, as well as driving behavior following the consumption/use of alcohol or other drugs. The purpose of data collection is to evaluate the magnitude of the problem of drugged driving. Despite the potential sensitivity of this issue, the experience of the AHP/Carnevale team, with the concurrence of the Expert Panel, suggests that direct, clear and specific questions focused on drugged driving behaviors and attitudes can provide an accurate and comprehensive understanding of the topic. To reduce respondents' potential discomfort, only anonymous, aggregated data will be collected. While these questions remain potentially sensitive, the study team expects that respondents' concerns about this will be reduced because no PII will be collected which could connect any responses to specific respondents. Completion of the survey is entirely voluntary.

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS

The estimates of hour burden are based on pilot tests of the survey with eight (8) individuals; the survey is expected to take approximately 12 minutes, or .20 of an hour. The estimates are below in Table A.12-1.

Table A.12 - 1 ESTIMATES OF HOUR BURDEN

A.12 - 1 ESTIMATES OF HOUR BURDEN					
Study Material	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response*	Annual Hour Burden
Drugged Driving Survey	Drivers (18 years of age or older)	3,750	1	12/60	750

There is no direct cost to respondents other than their time; the annualized cost to respondents based on the most recent report from the Bureau of Labor Statistics on Current and earnings for all employees on private nonfarm payrolls (seasonally adjusted) is \$10.32.²⁷ Therefore the cost to each respondent to take the 12 minute survey (.17 of an hour) is \$2.06 per response. The annualized cost to respondents is detailed below in Table A.12 - 2.

Table A.12 - 2 ANNUALIZED COSTS TO RESPONDENTS

A.12 - 2 ANNUALIZED COST TO RESPONDENTS							
Study Material	Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Drugged Driving Survey	Drivers (18 years of age or older)	3,750	1	12/60	750	\$10.32	\$7,740

²⁷ Bureau of Labor Statistics, (February 2014). *Real earnings for January 2014*. Retrieved on March 5, 2014 from <http://www.bls.gov/news.release/realer.htm>

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

There are no capital expenditures associated with this project; AHP and Carnevale are using existing buildings, equipment and software for this project. There are no other cost burdens to respondents or record keepers.

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The annualized cost to the Federal Government for the proposed data collection effort is estimated to be approximately \$280,440 as detailed in Table A.14-1 below.

Table A.14 - 1 ANNUALIZED COST TO THE FEDERAL GOVERNMENT

Item	Salary	Fringe Rate	% Effort	Annualized Cost
NIH Project Oversight Officer - GS15-9	\$158,700	20%	1.5%	\$23,805
4 prime contractor staff	\$377,862	39%	25%	\$210,000
4 sub-contractor staff	\$445,700	23%	21%	\$153,000
3 sub-contractor staff	\$362,065	42%	6.5%	\$30,000
Operational Costs for Data Collection Activities (Printing, mailing, web site costs, overhead), non-labor				\$43,000
Costs for purchasing gift cards for incentives				\$38,162
Travel costs associated with data collection				\$1,000
Other costs, non-labor				\$600
Total				\$499,567

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new collection of information.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

A.16 - 1 PROJECT TIME SCHEDULE	
Activity	Time Schedule
DMVs distribute stickers and/or postcards to recruit respondents	1 - 2 months after OMB approval
Respondents take Drugged Driving Survey (DDS)	During the 4 - 6 month period after OMB approval
Validation and discussion of data with state DMVs and other highway safety staff	6 - 12 months after OMB approval
Analysis of data collected from DDS	During the 6 - 12 month period after OMB approval
Publication of reports to states, municipalities, prevention programs, etc. as well as presentations at conferences and development of articles for peer-reviewed journals and trade publications.	18 - 24 months after OMB approval

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The OMB expiration date will be displayed on each instrument form.

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

No exception to 5 CFR 1320.9 is sought.