**Supporting Statement: Section A**

*Crash Risk Associated with Drug and Alcohol Use by Drivers in Fatal and Serious Injury Crashes*

## Background

The National Highway Traffic Safety Administration (NHTSA) is conducting this study on the risk of being seriously- or fatally-injured in a motor vehicle crash when a driver is drug- or alcohol- positive. It focuses only seriously/fatally injured drivers to build from past research and expand and enhance our understanding of the extent to which selected drugs and alcohol increase the risk of crash involvement.

A quantitative relationship between blood alcohol concentration (BAC) and motor vehicle crash risk was not well established until publication of the "Grand Rapids Study" in 1964.[1] This study provided compelling evidence that moderate BAC levels were associated with increased crash risk, and that risk grew exponentially at BACs of 0.10 g/dL or higher.[2] NHTSA conducted a study between 1996 and 1998 at Long Beach, California, and Fort Lauderdale, Florida to examine the relative crash risk of various BACs and confirmed the results of the Grand Rapids Study using modern data collection and statistical techniques.[3]

Much less is known about the prevalence and crash risk of drugs other than alcohol in drivers. More information is needed to inform policy considerations as States are beginning to support medical and recreational use of once controlled substances such as marijuana. The information on drivers using drugs generally comes from self-report surveys such as the National Survey on Drug Use and Health (NSDUH), from studies of the prevalence of drugs in fatal crashes, and from injury-producing crashes.[4,5] According to the 2009 NSDUH, approximately 10.5 million people aged 12 or older reported driving under the influence of illicit drugs during the prior year. The rate was highest at 12.8% among young adults aged 18–25.[6] Other research has shown that respondents typically underreport controversial behavior, such as drug use and driving. According to the 2007 National Roadside survey, only 25.7% of drivers who actually tested positive for THC reported using THC within the past 24 hours.[7] Similarly, only 7.5% of drivers testing positive for

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[1] Borkenstein, R. F., Crowther, R. F., Shumante, R. P., Ziel, W. B., & Zylman, R. (1964). *The role of the drinking driver in traffic accidents*. Bloomington, IN: Department of Police Administration, Indiana University.

[2] Borkenstein, R.F., Crowther, R.F., Shumate, R.P., Zeil, W.W., and Zylman, R. (1974). The role of the drinking driver in traffic accidents, 2nd e. *Blutalkohol; Alcohol, Drugs and Behavior*, 11 (Supplement 1).

[3] Blomberg, R. D., Peck, R. C., Moskowitz, H., Burns, M., & Fiorentino, D. (2005). Crash risk of alcohol involved driving: A case-control study. Stamford, CT: Dunlap & Associates, Inc.

[4] Terhune, K.W., Ippolito, C.A., Hendricks, D.L., Michalovic, J.G., Bogema, S.C., Santinga, P., Blomberg, R. and Preusser, D.F. (1992). The Incidence and Role of Drugs in Fatally Injured Drivers. Report No. 808 065. Washington, DC: National Highway Traffic Safety Administration.

[5] Soderstrom, C. A., Ballesteros, M. F., Dischinger, P. C., Kerns, T. J., Flint, R. D., & Smith, G. S. (2001). Alcohol/drug abuse, driving convictions, and risk-taking dispositions among Trauma Center patients. Accident Analysis & Prevention, 33(6), 771–782.

[6] Substance Abuse and Mental Health Services Administration. (2010). 2009 National Survey on Drug Use and Health. Rockville, MD: Office of Applied Studies.

[7] Lacey, J. H., Kelley-Baker, T., Furr-Holden, C. D. M., Voas, R., Romano, E., Ramirez, A., Berning, A. (2009). 2007 National Roadside Survey of Alcohol and Drug Use by Drivers: Drug Results (DOT HS 811 249). Washington, DC: National Highway Traffic Safety Administration.

cocaine reported using cocaine within the last 24 hours. These drivers agreed to be tested for drugs but did not acknowledge drug use in the survey. Self-report data, which may be useful in tracking trends in driver reports of drug use, may underestimate actual drug consumption activity. Accurately measuring drugged driving is especially of concern as the most recent roadside survey in 2013-2014 found an increase in the prevalence of THC in drivers from 8.6% in 2007 to 12.6%.[8]

An example of a study collecting biological specimens–the European Integrated Project, Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) study–involved roadside data collection across nine European countries to determine the prevalence of psychoactive substances in the general driving population.[9] Researchers analyzed biological specimens from more than 37,000 randomly selected drivers and 3,600 drivers who were seriously injured or killed in crashes. Alcohol was the most frequently detected substance in the driving population and in drivers seriously injured or killed. THC was the most frequently detected illicit drug in crash-involved drivers. The greatest risk of serious injury or death was associated with driving with alcohol concentrations in the blood greater than or equal to 1.2 g/L (.12 g/dL), or alcohol combined with other drugs. Both of these conditions placed drivers at relative risk levels of serious injury or death that were anywhere from 20-200 times greater than drivers in the control group. Multiple drug use, use of amphetamines, BAC greater than or equal to 0.8 g/L (.08 g/dL) but less than 1.2 g/L all respectively placed drivers at relative risk levels that were 5-30 times greater than the general driving population. Driving with cannabis or with alcohol in the blood greater than or equal to 0.1 g/L but less than 0.5 g/L placed drivers at relative risk levels that were 1-3 times greater than the general driving population which represents a slightly elevated crash risk.

No such large-scale studies of drugs and motor vehicle crashes had been conducted in the United States until very recently. A NHTSA-sponsored study in Virginia Beach, Virginia used a case-control design to provided ground-breaking research in a first look at the crash risk of various licit and illicit drugs.[10] That study's results including unadjusted odds of a crash if a person tested positive for a single drug, or combination of drugs. The initial analyses of the data suggested increased crash risk for some drugs, including marijuana. However, the analyses did not include other variables such as driver age and sex which are often important factors in highway safety studies. After adjusting for these demographic variables and the presence of alcohol in a person's system, the results indicated that none of the drug classes other than alcohol were associated with a statistically significant increased risk of a crash. This highlights the need for collecting demographic information for studies of this type. Without the additional analyses, very different conclusions would have been reached, leading to potentially different policy recommendations.

In the Virginia Beach study, the majority of crashes involved property damage only. Thirty-three percent of the crashes involved a driver injury (although not usually serious) and 0.6% included a driver fatality. This current study looks to progress along this line of research by focusing only on those crashes where the driver was seriously or fatally injured because little is known about how drug use plays a role in these kinds of crashes.

[8] Berning, A., Compton, R., & Wochinger, K. (2015, February). Results of the 2013–2014 National Roadside Survey of alcohol and drug use by drivers. (Traffic Safety Facts Research Note. Report No. DOT HS 812 118). Washington, DC: National Highway Traffic Safety Administration.
[9] Hels, T., Bernhoft, I. M., Lyckegaard, A., Houwing, S., Hagenzieker, M., Legrand, S., Verstraete, A. (2011). Risk of injury by driving with alcohol and other drugs. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines).
[10] Compton, R.P. & Berning A. (2015). Drug and Alcohol Crash Risk. Report No. DOT HS 812 117. Washington, DC National Highway Traffic Safety Administration.

For the current study, the participating trauma centers will provide NHTSA with biological specimens and de-identified information (e.g., demographics, medications administered by Emergency Medical Technicians prior to arrival, crash location) from an estimated 2,350 injured drivers who are transported by emergency medical services to one of three trauma centers. The local medical examiners will provide similar de-identified biological specimens and information for an estimated 150 fatally injured drivers. The research team will recruit anonymous non-crash involved "control" drivers at or near the location of the crash where a study driver was seriously injured or killed. Researchers will match control drivers on crash day of the week, time of day, and direction of travel. NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide only aggregate (summary) statistics and tables as well as the results of statistical analysis of the information; there will be no reporting of individual case information, including any personal information. The technical report will distributed to a variety of audiences interested improving highway safety.

Ultimately, NHTSA will use the information gained in this study to inform recommendations to the public and policy makers regarding any extent to which drugs may increase the risk of motor vehicle crashes that involve serious injuries and fatalities.

## A. JUSTIFICATION

The National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation (USDOT) is seeking approval from the Office of Management and Budget (OMB) to conduct a data collection effort to determine how drugs, including alcohol, may increase the risk of motor vehicle crashes that involve serious injuries and fatalities. Undertaking this important research will support NHTSA's mission to save lives, prevent injuries and reduce economic costs due to road traffic crashes, through education, research, safety standards and enforcement activity.

### A.1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

***a. Circumstances making the collection necessary***

NHTSA was established to reduce deaths, injuries, and economic losses that result from motor vehicle crashes on the Nation's highways. The agency develops, promotes and implements educational, engineering, and enforcement programs with the goal of ending preventable tragedies and reducing economic costs associated with vehicle use and highway travel. Current data is essential to develop future approaches to improve traffic safety. This is especially true for information on drug use and driving, where data is much more limited than regarding alcohol-impaired driving. On March 15, 2018, NHTSA's Deputy Administrator Heidi King held a summit on drugged driving as a "Call to Action," to move forward in setting a course of action to address the nation's drugged-driving problem.

Drugs affect biology, perception, psychomotor ability and behavior. With the exception of alcohol, relatively little is known about the prevalence of drugs in drivers, or about the relationship of drugs to crash risk. NHTSA and other research agencies have sought to learn about these issues through varied methodological approaches, including dosing studies, and

analyses of arrest and fatality data. This study provides the strongest research method, a case-control study, to examine relative crash risk associated with several drug categories including over-the-counter, prescription, and illegal drugs. The case-control approach is widely used in medical and epidemiological research when a person who already has a disease or other outcome of interest is compared to people who do not have the disease/outcome. Such studies compare the frequencies of exposure to risk factors to determine the relative risk of having a disease/outcome when exposed to the risk factor. In this study, the disease/outcome of interest is an injury that occurred while a person was driving a motor vehicle. The risk factors in this study are the drugs found in the drivers' systems after an injury/fatal crash.

To obtain data from seriously injured and fatality crash-involved subjects, we will obtain blood samples from the three participating trauma centers. As part of their normal emergency care activities, Level I trauma centers such as these collect blood samples directly from all patients, including crash-involved drivers, immediately upon arrival. The trauma centers order lab tests on the samples as needed throughout treatment. Because it is initially not known how many medical tests will be run for a given patient, more blood is drawn than is generally needed. While methods for the blood draws may vary slightly across trauma centers (some initially fill a single large syringe while others fill smaller, individual tubes directly), a residual sample is almost always available for research purposes. This study will use those already de-identified samples, under their availability to us per the Common Rule[11] that regulates the use of biological specimens in federally-funded research.

Similarly, the medical examiners collect blood for autopsy purposes and residual blood is available for research purposes. The participating trauma centers and medical examiners have agreed to provide these de-identified samples of blood and de-identified information (e.g., demographics, drugs administered prior to arrival, crash location) to the study. These samples, along with the blood samples collected anonymously from control drivers later will allow matched comparisons, which will result in risk estimates for each drug tested.

In 2010 and 2011, NHTSA conducted the first large-scale and carefully controlled study in the U.S. designed to estimate the relative crash risk associated with drug use by drivers.[10] The Virginia Beach crash risk study used a case-control design and included a variety of police-reported crashes. Because all types of crashes were included, a large percentage (66.4%) were property damage-only. Only one other study has attempted to estimate the risk of alcohol and drug use by drivers involved in more serious crashes (injury or fatal crashes).[9] That European study had several methodological limitations, and did not test for all the drugs of interest for NHTSA.

For the current study, NHTSA will collaborate with trauma centers to collect de-identified data from injured crash-involved drivers immediately after the crash. Trauma centers frequently encounter seriously- and fatally-injured drivers and routinely draw blood for medical, and also for research purposes under their standard treatment procedures - Level 1 trauma centers engage in clinical research as part of their mission. For example, a previous study was conducted in Level-1 trauma centers to determine the incidence and prevalence of alcohol

[11] Department of Health and Human Services (January 19, 2017). Federal Policy for the Protection of Human Subjects: Department of Transportation 49 CFR Part 11. *Federal Register, Rules and Regulations. Vol. 82, No. 12*; pp 7149 – 7274.

and other drug use among motor vehicle crash victims.[12] However, trauma centers could not conduct this type of research on their own because crash risk cannot be estimated without control sampling to compare results to the information from the crash-involved drivers. Therefore, NHTSA's case-control approach must be used to estimate crash risk associated with the drugs of interest. NHTSA has vast experience with collection of biological samples at roadside, including the development of protocols, training of researchers, collection of sensitive information, and ensuring privacy and anonymity. NHTSA's expertise is vital to gathering the needed information, and working with the experienced research teams at the trauma centers to conduct the best investigation into the relationship of drugs to the risk of being seriously or fatally injured in a motor vehicle crash.

Ultimately, this study will allow NHTSA to learn more about the relationship of drugs to crash risk. The large sample of seriously and fatally injured drivers gathered by this project will lead to a better understanding of the relative crash risk of drug involved driving for the most serious crashes. The results of this project will assist NHTSA in determining how different drug classes are related to driver safety which will help the Agency provide guidance to the States and Federal Government as each considers policies related to drug-involved driving.

***b. Statute authorizing the collection of information***

**Title 23, United States Code, Chapter 4, Section 403** gives the Secretary authorization to use funds appropriated to carry out this section to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information needed to carry out this section, with respect to all aspects of highway and traffic safety systems and conditions relating to - vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety, including impaired driving. [See 23 U.S.C. 403(b)(1)(A)(i), 23 U.S.C. 403(b)(1)(A)(ii), 23 U.S.C. 403(b)(1)(B)(ii)].

**A.2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

This is a new collection of information focusing on seriously and fatally injured drivers. The study will employ a case-control design that involves comparing two sampled control drivers not involved in a crash for every severely/fatally injured driver. This approach allows for the most accurate estimate of crash risk associated with the tested drugs. No similar study in the United States has focused on this population of drivers using this methodology. This new collection will address the substantial gap in knowledge regarding the risk of being seriously/fatally injured when using drugs while driving. NHTSA will use the information gathered to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personal information because none will ever be entered into the final analysis study database. The

[12] Walsh, J. M., Flegel, R., Cangianelli, L. A., Atkins, R., Soderstrom, C.A., & Kerns, T. J. (2004). Epidemiology of alcohol and other drug use among motor vehicle crash victims admitted to a trauma center. *Traffic Injury Prevention*, *5*(3), 254-60.

technical report will be shared with State Highway Safety Offices and other stakeholders interested in improving highway safety. Study results will be used by NHTSA to inform State and Federal policy on drugs and driving.

**A.3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical or other technological collection techniques or other information technology. Also describe any consideration of using information technology to reduce burden.**

The research team will create a computer application that will be installed on Windows® tablets for use by data collectors and the self-administered survey of control drivers. Running locally on a tablet, this data collection app will synchronize with a central database upon realizing a Wi-Fi connection. Computer tablets will be used by data collectors to both document/assemble on-site information (e.g., weather conditions, time of day) and administer self-report surveys to control participants. Study control participants will complete the survey using touch responses on the tablet. Data collectors may assist a participant if they are having difficulty reading items, understanding a question, or operating the device. Seriously or fatally injured drivers will not complete the survey.

This technology will minimize the burden on participants, improve the efficiency of collection and data management, help to preserve the integrity of biological and self-report sample data, and reduce the likelihood of data loss.

**A.4. Describe efforts to identify duplication. Show specifically why any similar information, already available cannot be used or modified for use for the purposes described in Item 2 above.**

This is the only study of seriously/fatally injured drivers that has utilized this case-control design to date in the United States. The DRUID study, conducted in several countries in Europe, sought similar information and included some similar data collection components. That study, however, did not implement as rigorous of a study design as that proposed here. The DRUID study also did not examine the full set of drugs that is important to NHTSA.

A key and unique feature of this study is that the crash-involved drivers must be transported to an emergency medical facility immediately after a crash and have a trauma team activated (i.e., “seriously injured”), or have died before or during treatment (i.e., “fatally injured”). Although others have investigated the prevalence of drugs in drivers, the methodological approaches of prior work have not obtained both crash-involved and drivers recruited at the scene of the crash at a future date. Furthermore, although NHTSA has recently conducted a similar case-control study involving drugged driving, the vast majority of crashes in that study were property damage only and did not lead to serious injuries or fatalities. In addition, NHTSA’s Virginia Beach study did not include a sufficient number of crashes on high speed roadways that yield more information about serious injury and fatal crashes. These types of high-speed crashes are included in this study.

**A.5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.**

The collection of information does not involve small businesses or other small entities.

**A.6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

The use of illicit and licit drugs while driving have major implications for driver safety. Little is known about the prevalence of drugs in drivers (with the exception of alcohol), and even less is known about the relationship of drugs to risk of serious injury in a motor vehicle crash. NHTSA has a responsibility to provide guidance to the public and policy makers about the potential dangers of drug-involved driving. Other Federal agencies, legislators, state highway safety offices, law enforcement agencies, and prosecution are looking to NHTSA for crash risk information on drugs. In this absence of this study, some use incomplete data and public concern to guide policy into strategies not based on evidence. This includes adoption of laws, enforcement strategies, and the local policies for the prosecution of drug-impaired driving.

In the immediate sense, delays to beginning data collection affect NHTSA's ability to retain a working relationship and data collection opportunities with the three trauma centers that have agreed to participate. The study has obtained approval from two IRBs which ensure all human subjects protections are being met as outlined in the Common Rule. The participating trauma centers are ready to begin and data collection can begin immediately upon approval from OMB.

This method of data collection for research within trauma centers is not novel. The samples are being collected under routine procedures for the collection of blood for clinical care. The risks, benefits and ethical considerations of the study have been carefully weighed by the investigators, research staff, and the two IRBs which have approved this project. It is common for trauma centers to collect residual blood for research purposes, in this case the samples for this study are being collected under an IRB-approved waiver of consent process. All samples for this study will be placed in tubes color-coded for this project, and trauma center staff will ensure the samples have been fully de-identified to protect patient privacy, and reduce burden on the participant population. This process and these human subject protections were discussed within the IRBs at length, and both IRBs approved of this protocol.

**A.7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.**

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

**A.8. Provide a citation for the FEDERAL REGISTER document soliciting comments on extending the collection of information, a summary of all public comments responding to the notice, and a description of the agency's actions in response to the comments. Describe efforts to consult with persons outside the agency to obtain their views.**

A copy of the 60-day Federal Register Notice, which notified the public of NHTSA's intent to conduct this information collection and provided a 60-day comment period, was published on July 17, 2017 (Vol. 82, No. 135, Pages 32757-8). The notice received one comment, which was from the Insurance Institute for Highway Safety (IIHS). IIHS expressed support for the study. As the commenter did not suggest changes, no revisions were made.

NHTSA has discussed this project with many other Federal agencies, including the National Institute of Drug Abuse and the National Institute of Alcohol Abuse and Alcoholism, and the President's Office of Drug Control Policy.

**A.9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

Control participants will be paid $5 for responding to survey questions and providing a breath alcohol sample. They will then be paid $50 for providing a blood sample. These payments to control participants are deemed necessary to provide sufficient incentive to participate for drivers recruited from free-flowing traffic. This level of incentive proved sufficient in NHTSA's prior drug studies which had similar protocols.[13,14] Extensive pilot testing was conducted as part of these past efforts and the $5 amount proved to be effective for maximizing participation rates for a survey and breath test. Pilot testing also revealed that $50 was a critical point at which participation rates reached an acceptable level for the blood sampling. Even with the $50 payment, experience from prior the NHTSA studies collecting blood at roadside suggests that only 55% of potential respondents will provide a blood sample. Providing the level of incentives described above is important to ensure adequate participation rates which are essential to the validity of the study findings.

For trauma center staff and medical examiners, it is existing routine practice to obtain a blood sample from each incoming trauma patient, including fatally injured drivers. Under the Common Rule guiding federal research studies, if these samples are de-identified, they can be used for research purposes without patient consent if the samples and any other information are de-identified. Additionally, as the trauma centers and medical examiners are providing de-identified samples and information to the study, no NHTSA staff or non-hospital contractor staff will be make contact with patients – thus more fully assuring participant anonymity and reducing burden. As such, incentive payments will not be made to the crash-involved participants.

[13] Lacey, J. H., Kelley-Baker, T., Furr-Holden, C. D. M., Voas, R., Romano, E., Ramirez, A., Berning, A. (2009). 2007 National Roadside Survey of Alcohol and Drug Use by Drivers: Drug Results (DOT HS 811 249).
[14] Compton, R.P. & Berning A. (2015). Drug and Alcohol Crash Risk. Report No. DOT HS 812 117. Washington, DC National Highway Traffic Safety Administration.

**A.10. Describe any assurance of confidentiality provided to respondents**

The study ensures each subject's privacy through several tiers of protection: 1) we are not collecting any personally-identified information; 2) blood samples will be stored in locked refrigerators with controlled access, 3) the laboratory results of the blood tests will not be known until after crash site information is destroyed; 4) the crash- and control-subject information will be stored in separate databases, with only subject numbers connecting the two sets of data, and 5) only aggregate-level data will be reported.

For the crash-involved subjects in the trauma centers or from the coroner's office, only designated medical staff will have contact with subjects to obtain the small sample of blood. For each sample drawn, this person will place a subject number on the vial, and place it in a secure research refrigerator in the hospital, in a space devoted to this study. Approximately once a week, these samples will be shipped to the toxicology laboratory. A toxicologist will then conduct a series of tests to determine whether each of the drugs of interest is present in the sample. The toxicologist will record the results for these tests, again only using the subject number. The toxicologist will not have any identifying information about the blood sample, and will not have any information related to the crash, or any information that could link any individual sample to any individual crash. The drug test results will be kept in the password-protected database, on a secure server.

For recruit control subjects, we need the location of the crash. The participating law enforcement agencies will send a list of crashes in their jurisdiction that occur to the research staff at the trauma center. The law enforcement agency will have already stripped all names from the crash information. For each crash-subject, the researcher will determine the location of the crash from the incoming information from the police and will record this location in a separate, "holding database" – another password-protector database on a secure server. A research team will be dispatched for the "case-controlled" data collection 1-week later, same time of day, same time of week, and as near the location of the crash, including the same direction of travel, as is safely possible possible. For these subjects also (who will have received a consent form, #1421), no identifying information will be requested or recorded, and only a subject number will be placed on the vial of blood. Once the small sample of blood is collected for the control drivers at that location, the researchers will place the samples in a secure research refrigerator. After the control data has been obtained for each location, the information about that location will be destroyed. With this action, there is no possible way for anyone to link an individual crash location with the results of a blood test, except for the subject number, which has no identifying information. These control-subject vials of blood will also be sent to the toxicology lab. Again, the toxicologist will not have any identifying information about the sample to be analyzed, and again only the subject number will be used to record the results of the drug tests.

As the research team conducts the statistical analyses, it will use the subject numbers to match crash-involved blood samples to the case-control blood samples, and these statistical analyses will yield the estimates of crash risk associated with the variable of interest – being alcohol- or drug-positive. As study results are prepared and disseminated, only aggregate categories will be used, such as "males had a crash risk of…." or "drivers under 21 had a crash risk of…"

**A.11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private.**

The survey does not contain any questions of a sensitive nature.

**A.12. Provide estimates of the hour burden of the collection of information on the respondents.**

Table 1. provides the numbers used to estimate the total burden. Total burden hours for the study will be approximately 1,800 over the two-year study period. Because the trauma centers and medical examiners will be providing the study de-identified information on injured drivers, research staff will not make contact with this population as part of the study. As such, the burden estimate is zero hours for the injured/killed drivers.

For the control sampling, NHTSA anticipates approaching an estimated 9,000 drivers at roadside with approximately 5,000 of the 9,000 agreeing to participate. This estimate is based on NHTSA's prior experience with a similar case-control study that collected blood at the roadside.[15] The time/burden estimates for each portion of the data collection are based on pilot testing recently conducted by the contractor using the tablet data collection system, and also from past experience collecting biological samples in the field.

**Table 1. Burden Hours Across Two Year-Study**

| Form # | Form Name (and associated activities) | Participants | Minutes per Participant | Burden Hours |
|---|---|---|---|---|
| FORM 1421 | CONTROL DRIVER VERBAL CONSENT | | | |
| | • Time for non-participating drivers with whom contact is made to hear about the study | 4,000 | 2 | 133 |
| | • Time for participating drivers to hear about study, and review and respond to all consent language | 5,000 | 5 | 417 |
| | • Time for the participating drivers to provide PBT sample and have a sample of their blood taken | 5,000 | 10 | 833 |
| FORM 1421 TOTAL | | | | 1,383 |
| | | | | |
| Form 1422 | CONTROL DRIVER QUESTIONNAIRE | | | |
| | • Time for the participating control drivers to take the questionnaire | 5,000 | 5 | 417 |
| FORM 1422 TOTAL | | | | 417 |
| | | | | |
| TOTAL BURDEN HOURS OVER 2 YEARS | | | | 1,800 |

[15] Lacey, J. H., Kelley-Baker, T., Berning, A., Romano, E., Ramirez, A., Yao, J… & Compton, R. (2016, December). Drug and alcohol crash risk: A case-control study (Report No. DOT HS 812 355). Washington, DC: National Highway Traffic Safety Administration.

The information below includes brief descriptions of the study protocols as they relate to the corresponding forms and burden estimates.

**FORM 1421: CONTROL DRIVER VERBAL CONSENT**

For the "Control" drivers at roadside –

- Drivers who do not participate: A researcher will ask a driver to provide informed consent to participate in a short survey, to provide a sample of their breath via a preliminary breath test (PBT) device, and provide a small sample of their blood. Pilot testing for the current study suggests it will take about 2 minutes for the initial study description and initial verbal consent process. Based on a previous NHTSA study with similar methodology,[12] it is estimated that 45% of drivers who are contacted at roadside will decline to participate. We estimate that to obtain the required sample size of 5,000 control drivers, there will also be approximately 4,000 individuals who listen to the initial study description and then decline to participate.

- Drivers who participate: A researcher will ask a driver to provide informed consent to participate in a short survey, to provide a sample of their breath via a preliminary breath test (PBT) device, and provide a small sample of their blood. It will take about 2 minutes for the initial study description and initial verbal consent process. Pilot testing suggests the remaining consent process will take approximately 3 minutes. NHTSA's prior experience with roadside collection of biological samples suggests it will take 10 minutes to complete the PBT sample and blood draw.

**FORM 1422: CONTROL DRIVER QUESTIONNAIRE**

For the "Control" drivers at roadside –

- Pilot testing on the new study tablets indicated the control driver questionnaire will take approximately 5 minutes to complete. The study requires full data collection for a sample of 5,000 control drivers.

## A.13. Provide an estimate of the total annual cost to the respondents or record keepers resulting from the collection of information.

This collection is solely reporting, and there are no record-keeping costs to the respondents. There is no preparation of data required or expected of respondents, thus there are no record keeping costs to the respondents. Participants do not incur: (a) capital and start-up costs, or (b) operation, maintenance, and purchase costs as a result of participating in the study.

If employed, costs to respondents for the planned collection of information by NHTSA can be calculated based on wages provided by the Bureau of Labor Statistics for All Occupations (http://www.bls.gov/oes/current/oes_va.htm#00-0000). This source indicates a mean hourly wage for all occupations of $25.53. If all respondents are employed, the total annual cost to respondents would be a maximum of $22,977 based on the calculation below:

**Table 2. Annual Cost Burden**

| Total annual estimated burden hours | Cost per Hour | Total Cost Per Year |
|---|---|---|
| 900 (1,800 hours divided by 2 years) | $25.53 | **$22,977** |

**A.14. Provide estimates of the annualized cost to the Federal Government.**

The actual data collection portion of this study is slated to take place over a two year period with a total of 7,500 fully completed participants (3,750 per each of two years). Total annual estimated cost to the Government for data collection for this study is as follows (note that this does not include costs for project administration, study design, data analyses or report writing):

**Table 3. Annual Cost to the Government**

| Item | Cost Per Year |
|---|---|
| Data Collectors: phlebotomists, surveyors, nurses, law enforcement ($45.33 loaded rate x 16,000) | $725,280 |
| Lab Fees ($110 x 3,750 crashed-involved and control participants) | $412,500 |
| Participant Payments ($55 x 2,500 control participants) | $137,500 |
| **TOTAL ESTIMATED COST TO GOVERNMENT PER YEAR OF DATA COLLECTION** | **$1,275,280** |

The estimated annual cost in terms of government time is approximately 120 hours for the Contracting Officer's Representative (COR) and 20 hours for the supervisor for about $9,000 in wages.

**A.15. Explain the reasons for any program changes or adjustments in Items 13 or 14 of the OMB 83-I.**

This is a new information collection. As such, it requires a program change to add the estimated hours for the new information collection to existing burden.

**A.16. For collection of information whose results will be published, outline plans for tabulation and publication.**

When study findings are published, no personal information will be included. All study records will be confidential. NHTSA plans to issue a final technical report on the study, and one or more journal articles may be submitted to refereed journals depending on the nature of the findings.

**A.17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

NHTSA will display the expiration date for OMB approval.

**A.18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions" of the OMB Form 83-I.**

No exceptions to the certification are made.