DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA-2019-0019]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on a proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under the procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA-NHTSA-2019-0019 using any of the following methods:

Electronic submissions: Go to http:// www.regulations.gov. Follow the on-line instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1-202-493-2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Amy Berning, Research Psychologist, NHTSA-NPD-130, 1200 New Jersey Avenue SE, W44-237, Washington, DC 20590. Ms. Berning's phone number is 202-366-5587, and her email address is amy.berning@dot.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the Federal Register providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

***Title*:** Prevalence of Alcohol and Other Drug Use Among Motor Vehicle Crash Victims Admitted to Select Trauma Centers

***OMB Control Number*:** None

***Form No.*:** None.

***Type of Information Collection Request*:** Approval of a New Information Collection

***Type of Review Requested*:** Regular

The research study will involve the use of information, including blood samples, that was originally collected in the course of clinical treatment. Generally, under 5 U.S.C. 1320.3(h)(5), information does not include "[f]acts or opinions obtained initially or in follow-on requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens." However, as provided in 5 U.S.C. 1320.3(h), OMB may determine that any specific item constitutes "information." NHTSA has consulted with OMB on a proposed research study and OMB has determined that, for the purpose of NHTSA's research study, the collection of the blood samples and de-identified information, including patient demographics, cause of injury, and injury severity, is a collection of information for which NHTSA must seek clearance from OMB.

Respondents: Participants will include approximately 7,500 people seriously injured in a motor vehicle crash (MVC) arriving at one of the selected trauma centers or morgues immediately after the crash injury was incurred. As such, participants will include seriously-injured and fatally-injured drivers and other crash-involved road users (e.g., passengers, pedestrians, bicyclists, scooter riders).

***Estimated Time per Participant*:** The trauma centers and medical examiners at the selected study sites universally draw patients' blood for clinical treatment or autopsy purposes. The trauma centers and medical examiners also collect other information such as patient demographics, cause of injury, injury severity, and drugs administered during treatment as part of their normal operating procedures. The only blood that will be used in this study will be de-identified blood samples that were collected, but not used, during their routine clinical procedures. The study will also use other de-identified information that was collected as part of their routine clinical documentation procedures. Again, this information would be collected even in the absence of NHTSA's research study. As such, NHTSA does not estimate any burden on the participants.

***Total Estimated Annual Burden Hours*:** 0.00 hours per year.

***Frequency of Collection*:** The collection is part of a one-time study. The trauma centers will provide de-identified information on a patient every time an individual presents to the trauma center as an MVC victim. When available, blood samples from MVC victims that were already collected as part of routine clinical procedures will be de-identified and provided for toxicological analyses. Similarly, the medical examiners will provide de-identified information on the fatally-injured MVC victims in the morgue and will provide a blood sample, when available, after all clinical procedures are complete.

Abstract: The National Highway Traffic Safety Administration (NHTSA) seeks to examine the prevalence of legal and illegal drugs in the systems of seriously- or fatally-injured drivers and other crash-involved road users presenting directly to the selected trauma centers or medical examiners. The contracted trauma centers and medical examiners will provide the study with de-identified blood samples, when available, that were already collected during their routine clinical treatment activities. The study will then conduct independent drug toxicology testing to determine the prevalence of alcohol and other drugs in the systems of the participants. The trauma centers and medical examiners will also provide the study with other de-identified participant classification information such as patient demographics, cause of injury, and injury severity. The trauma centers and medical examiners will provide this already-collected and de-identified information to the study in accordance with all applicable Federal, State, and local regulations governing the sharing of such information and as approved by the study Institutional Review Board.

Description of the Need for the Information and Proposed Use of the Information: NHTSA's mission is to save lives, prevent injuries and reduce traffic-related health care and other economic costs. The agency develops, promotes and implements educational, and enforcement programs with the goal of ending preventable tragedies and reducing economic costs associated with vehicle use and highway travel. There is a dearth of information on drug prevalence for seriously-injured MVC victims with only a couple studies exploring the issue in the United States (e.g., Walsh, et al., 2004[1]) and Canada (e.g., Brubacher et al., 2016[2]). This study seeks to help fill a gap

[1] 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.

[2] Brubacher, J., Chan, H., Martz, W., Schreiber, W., Abridge, M., Eppler, J., Lund, A., Macdonald, S., Drummer, O., Purssell, R., Andolfatto, G., Mann, R., & Brant, R. (2016). Prevalence of alcohol and drug use in injured British Columbia drivers. *BMJ Open*, 6(3), e009278.

in the state of knowledge concerning drug prevalence among MVC victims who are seriously- or fatally-injured, and present directly to a trauma center or morgue. While the sample is not nationally representative and will not be used for national estimates, the results of this research will produce information on a large sample of MVC victims, and will assist NHTSA in better understanding the prevalence of different drugs among the seriously- and-fatally-injured at the participating trauma centers and morgues.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

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Jon Krohmer,

Associate Administrator, Acting

Research and Program Development.

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